



Quality of Life of People with Diabetes Mellitus in Greece

A Thesis

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Declaration

I, Theodore Pisimisis confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

To

My loved ones Yiouly and Effie

Abstract

Diabetes is a chronic disease that influences almost all aspects of life of an individual, especially Quality of Life (QoL). This PhD thesis is the outcome of a research that aimed to assess the QoL of people with diabetes in Greece. The study is important because the area of diabetes-related QoL is generally understudied and is the first to have investigated this within the Greek population.

This work involved the creation of the Greek version of the Audit of Diabetes Dependent Quality of Life (ADDQoL-Gr) through translating, culturally adapting and validating the instrument as a QoL measure. The version was accepted by the author and the MAPI institute as the Greek version of the ADDQoL.

The QoL for people with diabetes in Greece was investigated using the ADDQoL-Gr. An assessment of their health status using the SF-36, as well as the relationship of QoL and health status with medical and socioeconomic factors was also investigated. 1027 diabetes patients participated in this cross-sectional analytical study from 8 different sites from central and northern Greece.

This thesis contributes to knowledge because i) identifies some characteristics of QoL predictors; ii) explores and prioritises QoL determinants; iii) reveals the complexity of the relationship between medical-socioeconomic factors and QoL; and iv) offers an instrument for measuring diabetes-related QoL for Greek speaking populations. The main conclusion drawn from this research was that diabetes seriously affects QoL, with complications (microvascular disease followed by foot amputation) having the most adverse effect.

The results of this thesis are important at both theoretical and practical level because: i) they add knowledge to the diabetes-related QoL international literature ii) may have important applications for the diabetes-care system; iii) they offer a validated instrument in Greek for future investigations.

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Theodore Pisimisis

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List of abbreviations

ADA	American Diabetes Association
ANOVA	Analysis of Variance
AWI	Average Weighted Impact
BDI	Beck Depression Inventory
BP	Bodily Pain (SF-36)
BS	Bradburn Affect Balance Scale
BSI	Brief Symptom Inventory
BULIT-R	Bulimia Test-Revised
CESD	Centre for Epidemiologic Studies Depression scale
DC	Diabetes Control
DCCT	Diabetes Control and Complications Trial
DCP	Diabetes Care Profile
DDS	Diabetes Distress Scale
DEP	Diabetes Educational Profile
DFBC	Diabetes Family Behaviour Checklist
DHP	Diabetes Health Profile
DKA	Diabetes Ketoacidosis
DQOL	Diabetes Quality Of Life measure
DSQOLS	Diabetes Specific Quality Of Life Scale
DUHP	Duke Health Profile
DUKE	Duke Health Profile
FA	Factor Analysis
FDA	Food Drug Administration
GDM	Gestational Diabetes Mellitus
GFI	Goodness of Fit Index
GH	General Health (SF-36)
GHb	Glycated Haemoglobin
GHP	General Health Perception index
GSI	Global Severity Index (sub-scale of BSI)
GW	General Well-being
HADS	Hospital Anxiety and Depression Scale
HbA _{1c}	Glycosylated Haemoglobin
HBM	Health Belief Model
HFS	Hypoglycaemia Fear Survey
HFS-W	Hypoglycaemia Fear Survey –Worry sub-scale
HRQoL	Health Related Quality of Life
HSS	Happiness and Satisfaction Scale
ICC	Intraclass Correlation Coefficient
IDDM	Insulin Dependent Diabetes Mellitus
IDF	International Diabetes Federation
IGT	Impaired Glucose Tolerance

MCS	Mental Component Summary
MH	Mental Health (SF-36)
MOS	Medical Outcomes Study
NA	Not Available
NHP	Nottingham Health Profile
NIDDM	Non-Insulin Dependent Diabetes Mellitus
NR	Not Reported
PAID	Problem Areas In Diabetes
PAIS	Psychological Adjustment to Illness Scale
PCA	Principal Component Analysis
PCS	Physical Component Summary (SF-36)
PF	Physical Functioning (SF-36)
QoL	Quality of Life
QSD-R	Questionnaire on Stress in patients with Diabetes-Revised
RE	Role Emotional (SF-36)
RP	Role Physical SF-36)
SCI	Self-Care Inventory
SCL	Symptoms Checklist – 90-R
SEIQoL	Schedule for the evaluation of individual QoL
SF	Social Functioning (SF-36)
SF-36	Medical Outcome Study 36-Item Short-Form Survey
SMBG	Self-Monitoring of Blood Glucose
SPS	Social Provisions Scale
s-r HbA _{1c}	Self-reported Glycosylated Haemoglobin
SRM	Standardised Response Means
STAI	State Trait Anxiety Inventory
T1D	Type 1 Diabetes
T2D	Type 2 Diabetes
UKPDS	United Kingdom Prospective Diabetes Study
VAS	Visual Analogue Scale
VT	Vitality SF-36)
WBQ	Well-Being Questionnaire

PART I: Review of the literature

Chapter 1: Overview

1.1 Introduction

Diabetes Mellitus (hereafter referred to as diabetes or DM) is a chronic and progressive metabolic disorder. Diabetes is of great importance to all health systems and it has been characterised as a global epidemic. The global prevalence of diabetes for those over 25 years of age, according to the World Health Organisation is 10%, while in the Eastern Mediterranean the prevalence is 11%. The costs of Diabetes account for up to 15% of national health care budgets (WHO, 2011).

Despite its importance and magnitude, the problem of diabetes has been treated by health systems mainly as a clinical problem (Glasgow *et al.* 1999). This one-dimension biomedical approach has resulted in neglect of other outcomes. Thus, the impact of diabetes on Quality of Life (QoL), behavioural, functional or economic outcomes has not received appropriate care (*ibid*).

Quality of life has become an endpoint in the evaluation of public policy (Brown *et al.*, 2004) and one of the major goals of medical care. As Patrick and Erickson (1988) argued:

“Enhancing quality of life is as important as other goals of health and medical care, such as preventing disease, effecting a cure, alleviating symptoms of pain, averting complications, providing humane care, and prolonging life”.

QoL and HRQoL belong to the concepts that W. Bagehot (1887) describes as “*we know what it is when you do not ask us, but we cannot very quickly explain or define it*”. Their definitions, and the various ways proposed for their measurement, are issues that have not been clarified. Definition of a concept is a major problem, especially for a concept such as Quality of Life, which is a vague and amorphous construct, and there is always the danger that has been described by the Greek Nobel laureate G. Seferis (1962) as a case where “*the definition displaces irreversibly the definiendum*”.

The wide acceptance of QoL as an idea, combined with its amorphous nature and the lack of a universally accepted definition, has resulted in confusion about the meaning

of the term. The various definitions proposed for each concept are explored in the relevant sections of this thesis. The concept of quality of life is analysed in terms of its origins, and the models of it proposed by writers of various disciplines. This thesis tries to clarify the term, review the existing definitions, and find the most suitable and operational definition for this project.

Also, terms such as “health”, “well-being”, “happiness”, “health related quality of life”, and “health status”, as well as the overlap between them, are examined. Finally, a decision had to be made on which definition of QoL and HRQoL would be the most suitable for assessing the HRQoL of the Greek diabetes population.

Improvement in the QoL of people with diabetes, together with its prevention and cure is part of the general goals of the St. Vincent Declaration for people with diabetes published in 1989. However, although progress has been made, significant gaps still exist in the implementation of the St. Vincent targets twenty years later (Felton and Hall, 2009). The task of improving QoL presupposes an identification of the possible determinants of diabetes related QoL and the impact that they might have on the lives of patients with diabetes. To this end the role of medical characteristics (e.g. diabetes type, glycaemic control, treatment regimen, duration of the disease, complications, and the quality of care that a patient receives) is examined, along with sociodemographic variables like gender, age, education level, marital status, and income level.

Despite the fact that there is a growing interest in the associations between QoL and medical, demographic, and psychosocial variables (Rubin and Peyrot, 1999), there are areas that have not received a lot of attention from researchers at the international level. Research that has taken place during the last 20 years, has underestimated the impact of diabetes on QoL (Norris *et al.*, 2011). Also, the impact of diabetes on low-income populations has been an under-studied subject area (Camacho *et al.* 2002).

An area that has also not received particular attention is the constraints on access to services in health care systems providing “universal coverage”. Such constraints are: obligatory co-payments, restrictions on specialty referrals, and proximity to health care facilities (Gold, 1998). Co-payments are a major issue in diabetes care in

Greece. The differences in the services and/or reimbursements provided by the Greek NHS and the various organisations of social security create the environment for such expenditure. As a result, there is a rapidly growing private and quasi-private diabetes-care sector.

Health care influences the disease process and therefore health outcomes in general can be affected by different methods of delivering care. Diabetes, as a chronic disease, is no exception to this rule (Bowling, 1995a; Fleming *et al.* 2001). However, the very structure of the diabetes care system and the geographical distribution of its services in Greece may restrict access. This, either on its own or combined with the financial burden that diabetes causes, could be proved to be associated with QoL. Despite the fact that care delivery is receiving increased attention, in Greece the association between this factor and QoL, as a health outcome, has never been investigated.

This study aims to examine the Quality of Life of people with diabetes in Greece and to what extent their self-assessed QoL is associated with demographic and socioeconomic factors.

My main motives for the initiating and conducting this research were:

- a) The alarming and ever increasing prevalence of the disease, that reaches epidemic proportions worldwide, combined with:
- b) The importance of QoL as a concept, which is “*the ultimate goal of all health interventions*” (Rubin and Peyrot, 1999);
- c) The fact that most of the studies on the impact of diabetes on QoL use health status measures;
- d) The fact that the determining socioeconomic factors of the diabetes-related QoL have been understudied;
- e) The fact that QoL, health status, and glycaemic control are almost used by Greek physicians as synonyms;
- f) That no similar study has ever been attempted in Greece, possibly due to lack of a reliable QoL instrument.

Chapter 2: Diabetes

2.1 Diabetes: a definition

Diabetes is a global health problem. It is one of the world's most important causes of expenditure, mortality, disability and lost economic growth (IDF, 2006).

Diabetes according to the World Health Organisation (WHO) is

“A metabolic disorder of multiple aetiology characterized by chronic hyperglycaemia with disturbances of carbohydrate, fat and protein metabolism resulting from defects in insulin secretion, insulin action or both. The effects of diabetes mellitus include long term damage, dysfunction and failure of various organs” (WHO, 1999).

2.2 Aetiology and Classification of diabetes

A number of specific causes of diabetes have been identified, but its aetiology and pathogenesis are not clearly understood (Bennett and Knowler, 2004). However, there are two major categories of pathogenesis. The first is caused by an absolute deficiency of insulin secretion, while the second has its causes in factors such as insulin resistance at the liver and muscles, and/or an inadequate insulin secretion response.

The first widely accepted classification of diabetes was published by the World Health Organisation in 1980. According to this diabetes was divided into two major classes: The Insulin Dependent Diabetes Mellitus (IDDM) or Type 1, and Non-Insulin Dependent Diabetes Mellitus (NIDDM) or Type 2. This classification was revised in 1985 when the terms Type 1 and Type 2 were omitted and remained only the terms IDDM and NIDDM (WHO, 1985).

The 1985 classification had the disadvantage of using a mixture of criteria, some related to the degree of insulin deficiency and others to pathogenesis. In a very influential report published by Kuzuya and Matsuda, a new classification was proposed, where the aetiology and the degree of deficiency and/or insulin action

should be considered separately and be both incorporated in the classification (Kuzuya and Matsuda, 1997). Subsequently, the World Health Organisation followed the Kuzuya - Matsuda proposals and revised the 1985 classification. It now classifies diabetes according to both clinical stages and aetiologic type (WHO, 1999). According to this classification the terms IDDM and NIDDM should be abandoned and the terms Type 1 and Type 2 reintroduced. Thus, since 2003 when some minor modifications that took place concerning mainly the diagnosis aspect, diabetes has been sub-divided into four clinical categories:

- Type 1 diabetes
- Type 2 diabetes
- Other specific types of diabetes
- Gestational diabetes

Types 1 and 2 are the basic forms of diabetes, while, the gestational and other specific types are more rare types (WHO 1999, ADA 2009aa). Symptoms of diabetes include thirst, polyuria, blurring of vision, weight loss and in severe cases drowsiness and coma. In almost all cases there are high levels of glycosuria. Many of them have no symptoms and are only diagnosed after many years of onset. As a consequence, 40-50% of all people with Type 2 diabetes are not aware that they have this life-threatening condition.

People who develop diabetes pass through several clinical stages. The stages are of variable duration, according to the degree of hyperglycaemia.

- The first stage is “impaired glucose regulation”, is a hyperglycaemic disorder that represents a transient stage between normoglycaemia and the development of type 2 diabetes but it is not diabetes;
- The second stage, “impaired fasting glycaemia”, which is used to classify individuals with glucose values above the normal range, but below those diagnostic for diabetes
- The third stage is “non-insulin requiring” diabetes;
- The fourth stage is “insulin required for control” diabetes and;

- The fifth stage is “insulin required for survival” diabetes. Failure to manage this stage can result in ketosis and/or ketoacidosis, both life threatening conditions (WHO, 1999; Bennett and Knowler, 2004).

2.2.1 Type 1 diabetes

The cause of type 1 diabetes is an absolute destruction of the β -cells, usually leading to absolute insulin deficiency. It is also called “Insulin Requiring for Survival” diabetes. Patients with this type of diabetes produce very little or no insulin, and require daily injections of insulin to survive. Type 1 diabetes accounts for only 5-10% of the total diabetes cases. The β -cell destruction is due to either an autoimmune pathologic process and is called Type 1 Autoimmune, or idiopathic reasons, the so-called Type 1 Idiopathic diabetes. Autoimmune destruction of β -cells has multiple genetic predispositions, identified by human leukocyte antigen (HLA), as well as being related to some unidentified but presumed environmental factors. The majority of Type 1 patients have Type 1 autoimmune diabetes.

Idiopathic type 1 diabetes has no known aetiologies, lacks immunological evidence for β -cell destruction, and it is not associated with HLA. It is a strongly inherited type of diabetes and it is more common among non-white people of African or Asian origin. Only a minority of type 1 patients belong to this form of diabetes.

Type 1 diabetes, if not treated can lead to ketoacidosis, which is the most severe acute complication, together with hypoglycaemia (the other extreme of the glycaemic spectrum), coma and death (WHO, 1999).

2.2.2 Type 2 diabetes

Type 2 diabetes is the most common type of diabetes. Type 2 accounts for 90-95% of the total diabetes population. It is characterised by a combination of resistance to insulin action and it ranges from insulin resistance with an inadequate compensatory

insulin secretory response, to insulin resistance with insulin secretory defect. The insulin secretion disorder is not due to β -cell destruction, but its aetiology is unclear. People with disorders in insulin action cannot use insulin effectively. Risk factors for this type of diabetes are considered to be age, obesity, and lack of physical activity.

There are two sub-divisions of type 2 diabetes. The “Not Insulin Requiring” diabetes, managed by lifestyle measures alone and sometimes oral drugs, and the “Insulin requiring for control” diabetes, where insulin is required for control, rather than survival (WHO, 1999; ADA, 2009b; Harmel and Mathur, 2004).

Unlike Type 1, Type 2 diabetes is a condition where the pancreas produces some insulin, so hyperglycaemia may exist on a chronic asymptomatic basis, and in most cases cannot be easily noticed until some complication occurs. Thus, although Type 2 diabetes does not usually provoke acute episodes, such as ketoacidosis, it may create severe chronic complications with a consequent impact on the individual’s health status and use of health services.

2.2.3 Other specific types of diabetes

There are several types of diabetes can be classified under this heading that (ADA 2009a).

- Those forms associated with genetic defects of the β -cells function. They are also referred as “maturity onset diabetes of the young” (MODY) and are characterised by impaired insulin secretion with minimal or no defects in insulin action;
- Genetic defects in insulin action. An unusual cause of diabetes that results from mutations of the insulin preceptors;
- Diseases of the exocrine pancreas, caused by any process that diffusely injures the pancreas;

- Endocrinopathies, where hormones such as cortisol, growth or epinephrine antagonise insulin action;
- Drug or chemical-induced diabetes, caused by drugs that impair insulin secretion;
- Infections, caused by various viruses;
- Uncommon forms of immune-mediated diabetes and ;
- Other genetic syndromes sometimes associated with diabetes.

2.2.4 Gestational diabetes (GDM)

Gestational diabetes is defined as glucose intolerance with onset or first recognition during pregnancy. This definition applies regardless to the treatment regimen or whether the condition continuous after pregnancy. GDM, as with all other types of diabetes, is characterised by insufficient β -cell function and its causes belong to the same spectrum of the other types of diabetes i.e. autoimmune disease, insulin resistance, genetic causes etc. (Buchanan *et al.* 2007; ADA, 2009b).

There is recent evidence that GDM prevalence has increased by between 10-100% during the last 20 years among several ethnicity groups (Ferrara, 2007: S141). Increasing maternal age, obesity, lack of physical activity and changing lifestyles in the developing countries are the main causes for this increase (*Ibid*).

2.3 Prevalence of diabetes

2.3.1 Prevalence of diabetes globally

Diabetes and especially Type 2 diabetes is the most common endocrine disorder worldwide. Its prevalence is reaching epidemic proportions in many parts of the world. The International Diabetes Federation estimated that in 2007 the prevalence of Type 2 diabetes among adults of 20-79 years of age was 8.3% and the comparative

prevalence was 8.5% (IDF, 2013). The prevalence varies between countries, as well as within different strata or ethnicities of the same country. Thus, prevalence rates reported start from 1% in rural Malaysia up to 50% among the Pima Indians of Arizona- USA. The prevalence of total glucose intolerance (diabetes and IGT combined) for European and USA white populations ranges within 11-20%, while the percentage for Afro-Americans is 30% (King and Rewers, 1991).

The prevalence in the USA for the years 2005-2006, for people aged ≥ 20 years was 12.9%, of which around 40% was undiagnosed (Cowie *et al.* 2009). Between 33% (Franse *et al.* 2001) and 50 % (Rathmann *et al.* 2003) of the total diabetes population the condition may never be diagnosed.

In the European Union in 2008, diabetes prevalence was estimated at 8.6% of the population aged between 20 and 79 years. Its prevalence in 2005 was 7.6%, suggesting an absolute increase of 1% within 3 years. The 2008 prevalence rate equates to over 31 million people are now living with diabetes in the EU. Many of the people newly affected by diabetes are from vulnerable groups of society, including children and immigrants (IDF, 2008).

2.3.2 Prevalence of diabetes in Greece

In Greece the estimated number of diabetes-patients is around 800,000. The prevalence of diabetes in the urban population is 7.6% in men and 5.9% in women. Total prevalence in rural populations is estimated at 7.4% with 7.1% for men and 7.6% for women, while 2.5% of the total population had diabetes but are unaware of their condition (Melidonis *et al.* 2006). Other studies suggest the prevalence of diagnosed diabetes is 8.7% to 9.5%, but the data collection methods of these studies were unsatisfactory (Gikas *et al.* 2004, 2008). A remarkable feature of the diabetes population in Greece is that a significant proportion (24% of men and 30% of women) of these patients was undiagnosed (Panagiotakos *et al.* 2005).

2.4 Complications of Diabetes

2.4.1 Introduction

Diabetes complications are divided into two main categories: micro vascular, which include neuropathy, retinopathy and nephropathy (renal damage) and macro vascular diseases including coronary artery disease, peripheral vascular disease, hypertension and stroke.

2.4.2 Diabetic Neuropathy

Diabetes may cause major damage to the nervous system. Diabetic neuropathy is the most common complication. According to the World Health Organisation up to 50% of people with diabetes are affected to some degree (WHO, 2009). Major risk factors for this condition are the level and duration of elevated blood glucose. Neuropathy can lead to a variety of other complications such as sensory loss and damage to the limbs. It is also a major cause of impotence.

2.4.3 Foot disease

Diabetic foot disease is due to changes in blood vessels and nerves and often leads to ulceration and sepsis resulting in lower- limb amputation. Diabetes is the most common cause of non-traumatic amputation of the lower limb. Recent studies estimate that the amputation risk is eight times higher in diabetes compared with non-diabetes individuals. (Johannesson *et al.* 2009). Major amputations are considered to have a large impact on physical and psychosocial health status (Peters *et al.* 2001). They are also considered to be one of the most costly complications of diabetes (Williams *et al.*, 2002) and the single most important complication as far as direct economic cost is concerned (Matricali *et al.* 2007).

2.4.4 Retinopathy

Diabetic retinopathy is a major cause of blindness and visual disability. In the UK it is the leading cause of blindness in people of working age (NHS 2007). Research findings suggest that, after 20 years from onset, retinopathy develops in almost all patients with type 1 and 77% of those with type 2 diabetes. 12% of type 1 diabetes patients with more than 30 years from onset are blind (WHO, 2006; Klein and Klein, 1995). Diabetes is also among the leading causes of kidney failure, but its frequency varies between populations and is also related to the severity and duration of the disease.

2.4.5 Cardiovascular Diseases

Cardiovascular diseases represent the leading cause of morbidity and mortality in the diabetes population globally. The risk of coronary heart disease for patients with type 2 diabetes is two to four times higher compared with non-diabetic individuals (Haffner, 2000). The International Diabetes Federation estimates that cardiovascular diseases are responsible for 50 to 80% of deaths in people with diabetes globally (IDF, 2007). Mortality of people with diabetes aged 30-59 years is up to five times higher compared to non-diabetic people (Saydah *et al.* 2002; Roper *et al.* 2002). In the USA mortality of people with diabetes due to cardiovascular causes lies between 75% and 80% of total mortality. (ADA, 1993). Risk factors for heart disease in people with diabetes, are similar to those of the general population, and include high blood pressure, high serum cholesterol, obesity and smoking. At any level of these risk factors diabetes patients have four to five times the risk of cardiovascular disease compared with individuals without diabetes (*ibid*).

2.4.6 Diabetic Nephropathy

High blood glucose and high blood pressure may cause damages to micro blood vessels of the kidneys. The ADA estimates that nephropathy will occur to 20-40% of diabetes patients and that it is the leading single cause of end-stage renal disease (ADA, 2009a).

2.5 Diabetes care

There are two levels of care for diabetes; prevention and treatment of diabetes.

2.5.1 Diabetes and prevention

Diabetes prevention includes the prevention of the development of diabetes, early detection, prevention, and treatment of diabetes and its complications. Primary prevention identifies and protects individuals at risk from developing diabetes. It consists of lifestyle changes, such as changes in nutrition, food labelling, loss of weight, increased physical activity and participation in health education programs. Secondary level of prevention includes early diagnosis and control of diabetes in order to delay the progress of the disease. Early diagnosis includes screening programmes to detect asymptomatic individuals. Tertiary prevention refers to prevention or the early detection of complications in order to reduce the impact of the disease and the need for treatment. To this end diabetes patients should have an effective control of blood-glucose level and blood pressure as well as receive care on a regular basis from a number of health professionals with various specialties. A specialised physician should be the coordinator of a team that ideally consists of a diabetes nurse, dietician, pharmacist, physicians' assistants and mental health professionals specialised in diabetes.

Effective tertiary prevention has been proved by several studies to have a substantial effect on reducing the development of complications. Two major studies undertaken in the U.K., the Diabetes Control and Complication Trial (DCCT) and the UK Prospective Diabetes Study (UKPDS) have proved that intensive control of blood-glucose level and blood pressure led to substantial reduction of complications. Thus, the risk for the development of retinopathy was reduced by up to 76%; for neuropathy the risk reduction was up to 60%; for nephropathy the risk was reduced by up to 50%; for microvascular diseases 25%; and the overall reduction of mortality due to long term complications was 33% ((DCCT, 1993; UKPDS, 1998a; UKPDS, 1998b).

2.5.2 Treatment of diabetes

Despite the fact that a cure for diabetes is not possible for the moment, there are many forms of highly effective treatment. Before any treatment begins a thorough evaluation should be performed, in order to determine the type of diabetes, to detect the existence of any complications and to review any treatments that the patient received. This evaluation is necessary to ensure the optimal management of the patient. It should also be noted that patients' active participation is considered necessary for the management of this chronic disease.

Treatment of diabetes is associated with good diabetes control which in turn means keeping the blood-glucose level as close as possible to the normal level. Intensive blood-glucose monitoring is the basis for any effective treatment of either type of diabetes. Diabetes control may be achieved by a controlled diet, physical exercise, and/or medication. Dietary control is needed to reduce the intake of sugar, and physical exercise to help the body to use blood sugar efficiently.

Medication comes under two main categories: oral hypoglycaemic drugs and insulin. For type 1 diabetes patients insulin is necessary for survival. People with type 2 diabetes may require either oral drugs and in some cases insulin. There are four main types of insulin depending mainly on the onset and the duration of action: the rapid-acting insulin, the short-acting, intermediate-acting, and long-acting insulin.

2.5.3 Access to care

Access to health care contributes to improvements in health and the relief of illness (Gulliford *et al.* 2003). It is also one of the concepts that constitute the notion of equity in health care (McGuire *et al.* 1992). As such it is one of the four components, together with effectiveness, acceptability and efficiency, that a definition of quality of health care should include (Higginson 1994). Access has two dimensions; geographical distance between the patient and the provider, and the waiting time needed for the provision of services.

Aday and Andersen (1981) define access in terms of the “*dimensions which describe the potential and actual entry of a given population group to the health care delivery system*”. From this ‘access to care’ would include the ‘potential access’, which concerns the availability of services and the ‘realised access’ that is the use of those services by patients. Realised access includes objective and subjective indicators of the process of seeking care (Aday *et al.* 2004), and may be constrained or influenced by various factors such as structural, financial, and personal barriers. Proximity to providers, health-insurance coverage, gatekeeping, required co-payments, income, education and culture are some of the factors that fall into those three broad categories of barriers (Gold, 1998).

It is estimated that in the USA up to 40% in some cases of adults having diabetes were undiagnosed (Cowie *et al.* 2009). According to Zhang *et al.* (2008) this is mainly a matter of restricted access to diabetes care. Lack of adequate insurance coverage is the main cause of this limited access and the effect of what call they call ‘the missed patient with diabetes’ is an unseen but clinically important burden of diabetes, with significant metabolic derangements and long term impact on health care use.

The problem of access has another dimension that has received a lot of attention lately. This is the question of ‘open access to diabetes care against the pre-scheduled appointments (Murray and Berwick, 2003). Open access is possible when the providers’ capacity matches patients’ demand for appointments. Proponents of open access argue that this strategy eliminates unwanted delays for appointments, increases clinical productivity, and increases patient satisfaction. However, the case of diabetes as a chronic disease seems to be different. Recent research in diabetes settings concludes that what matters most for the quality of care is not open access, which in some cases might worsen outcomes (Subramanian *et al.* 2009), but continuity of care, which is associated with improvements in diabetes control (Sperl-Hillen *et al.* 2008).

Last, it should be mentioned that as far as diabetes is concerned access to diabetes-education is of great importance to the health and well-being of diabetes patients.

Nevertheless, this is an undervalued function of health systems. Peyrot *et al.* (2009) state that there are several important barriers that reduce access to diabetes self-management education and as a result only one third to one half of persons with diabetes in the US receive this critically important service. These barriers include lack of insurance coverage, residence in rural areas, and lack of social networks.

2.5.4 Diabetes-care organisations

Diabetes, as a chronic disease, presents a set of challenges to patients including dealing with symptoms, emotional impact, disability, complex medication regimens, lifestyle adjustments, and the use of quality medical services. However, health care systems are historically oriented to respond rapidly and efficiently to acute disease or injury and not to chronic illnesses like diabetes, which requires a wide delivery system with coordinated actions and productive interaction with the patients, and modern technology (Wagner *et al.* 2001b).

Quality of care is one of the major goals in the St. Vincent Declaration. The relative weight of medical care for improving health in general is a controversial issue and the answer rather depends on both the nature of the disease and the level of development of the health care system. However, in a chronic disease like diabetes, it is accepted that medical organisations influence the process of care, which in turn influences health outcomes (Fleming *et al.* 2001). The ways that these organisations influence outcomes varies ranging from the identification of persons with undiagnosed diabetes, to the provision of effective treatment, and patient education.

The question about the level and organisation of services that should deliver diabetes care is an old one with no conclusive answers (Wagner *et al.*, 1996; Renders *et al.* 2001). There is a generally accepted view that diabetes control is more effective when executed by a consultant than a General Practitioner (GP). However, good results have been obtained in settings where GPs collaborate with diabetes-nurses and dieticians in developing a strategy for treatment, education, diet, physical activity and any necessary interventions. Germany, Sweden, and the Netherlands

have been used as examples of this model of care (Van Loon *et al.* 2000). The participation of specialist diabetes nurses in diabetes care is also a field of controversy, although a review of literature has shown that there is no strong evidence of benefit of care provided by these specialists (Loveman *et al.*, 2009).

The initial optimism created by the St. Vincent Declaration about swift changes in quality of diabetes care was not justified. The implementation of programs necessary to bring about improvements in care was too slow and in some European countries twenty years later has not even begun (Hall and Felton, 2009).

2.6 Diabetes care in Greece

Diabetes care is provided by both state and private institutions. However, diabetes is not included in the priorities of the Ministry of Health and is treated as all other chronic diseases. There is not any kind of a national diabetes program addressing this major public health problem. As a result there is not any screening program for the general population and a significant proportion of people with diabetes population is undiagnosed (Panagiotakos *et al.* 2005). There are not any data concerning the diagnosis of diabetes, but diabetologists argue that routine blood tests is the main diagnostic method for both types of diabetes, while diabetic ketoacidosis is sometimes the way type 1 diabetes is diagnosed (Fig. 2). The tests usually take place at the NHS, social security and private sector primary care establishments (Fig. 1). However, the high cost of diabetes treatment forces the majority of patients to turn to social security and the NHS hospital clinics.

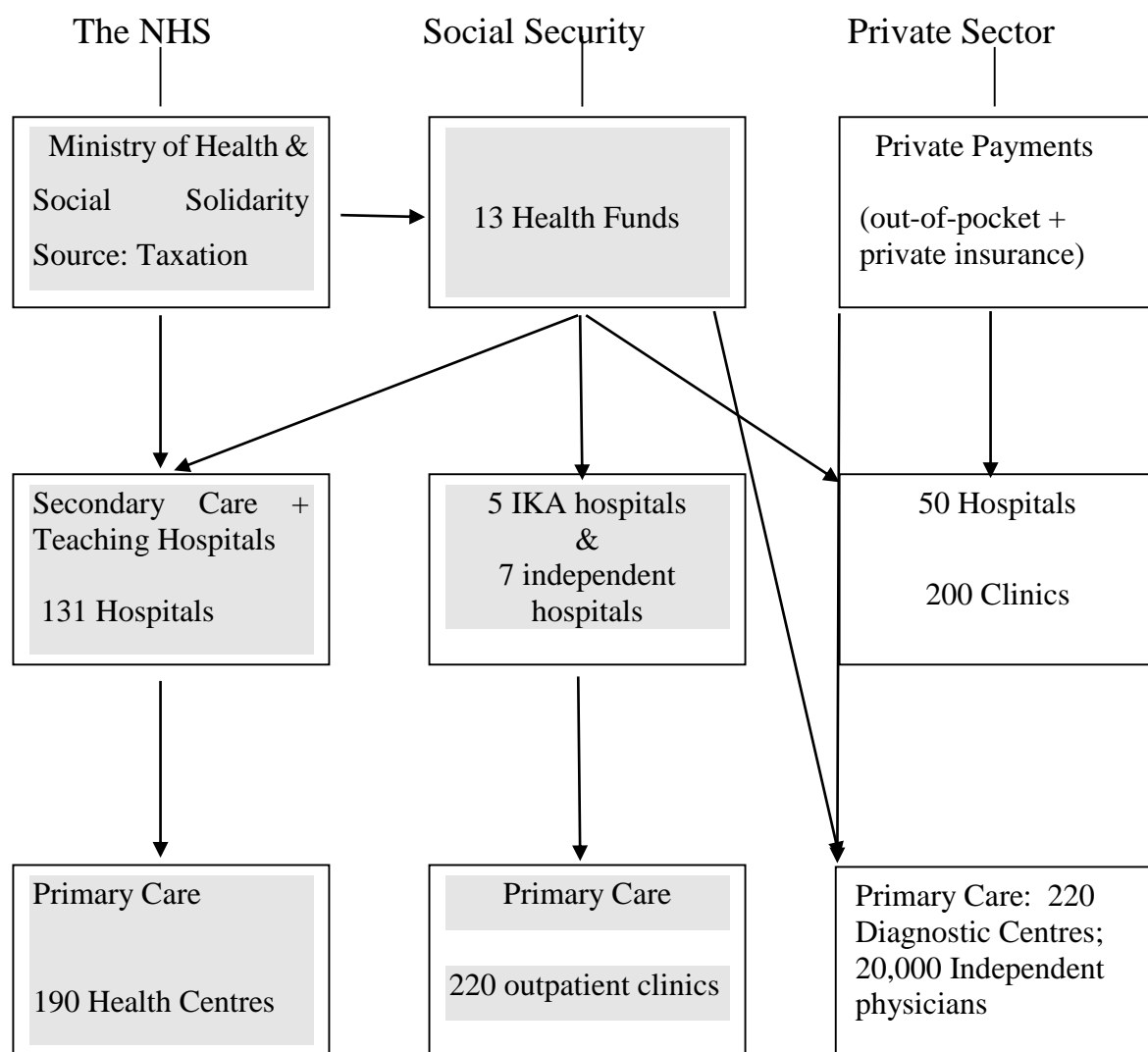
There are 131 state hospitals, but almost half of them do not provide any diabetes-care. There are only 17 diabetes centres in Greece twelve in Athens, three in Salonica, one in Patras, and one in Heraclion- Crete. Another 50-55 hospitals have a diabetes clinic, but most of them not on a permanent basis, depending on the availability of medical staff. The majority of them when they operate accept patients only one or two days a week.

Diabetology in Greece is a medical sub-specialty that can be obtained by attending one year education-training usually at a university hospital. To enter these courses a medical doctor should be either an endocrinologist, or internist, or a paediatrician. Medical doctors from other specialists are not allowed to participate in the courses. During the last years there is an increased pressure from various sources for general practitioners to be allowed to attend diabetes training courses. The total number of diabetologists in Greece is below the needed level.

Nurses are used to support daily procedures in outpatient diabetes clinics and provide elementary education to patients, mainly on injecting and blood testing techniques. These nurses have received “on the job training” by diabetologists at diabetes clinics, because diabetes nursing is not recognised by health authorities as a specialisation, there is not any education for it, nor they receive any kind of compensation or fringe benefit.

Dieticians are employed by all major hospitals in Greece with a general education on diabetes diet, but we did not find any dietician specialised in diabetes. Moreover, dieticians in hospitals are responsible for diets of acute care patients and do not have any cooperation with outpatient diabetes clinics. Psychologists specialised in diabetes are very rarely used by hospitals or other diabetes care institutions. During the course of this research only one diabetes centre (Polycliniki of Athens) was found with a psychologist among its staff.

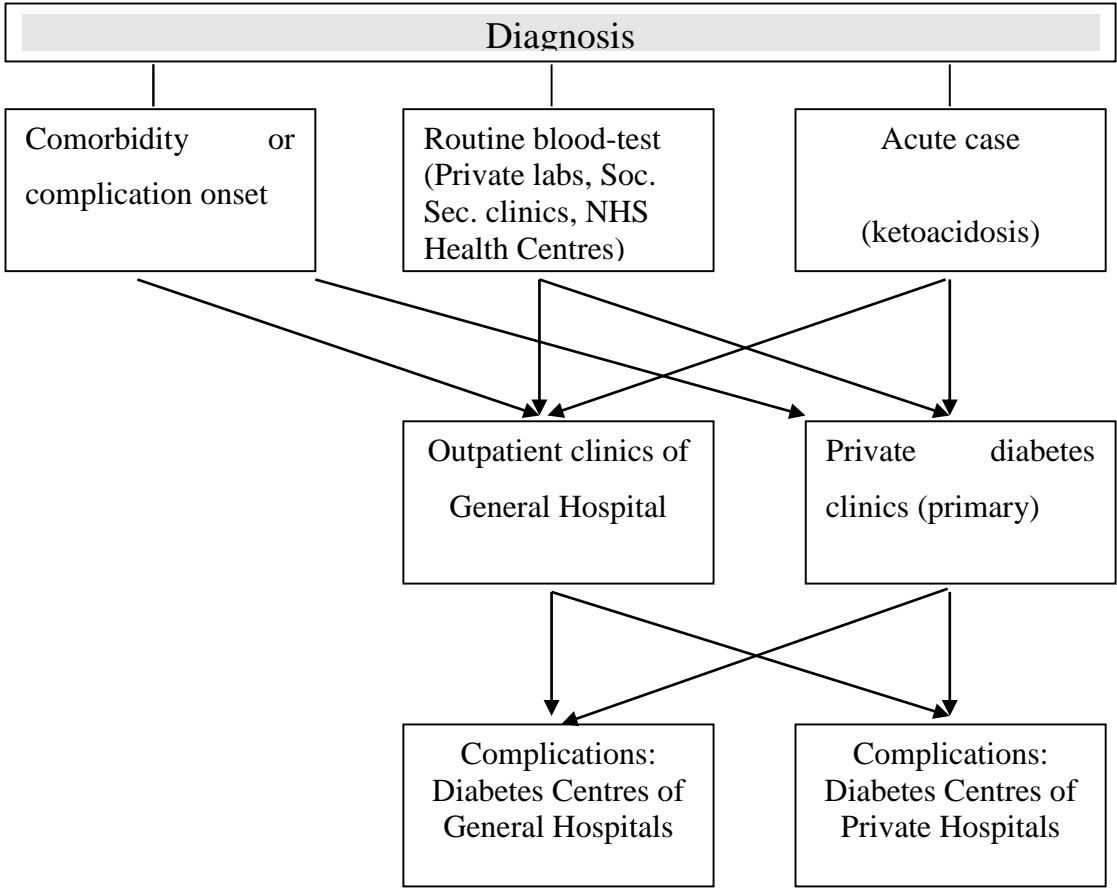
Fig 1: The Greek health system



→ Flow of payments

Public sector

Fig 2: The structure of Diabetes Care



→ : Flow of patients

Chapter 3: Quality of Life.

3.1 Introduction

Quality of Life (QoL) is an increasingly important concept. It is a multi-level, complex, and rather amorphous concept. Its importance was highlighted in the Stiglitz and Sen Report to the President of the French Republic (Stiglitz et al. 2009), where the two Nobel laureates and their associates suggested that

“Quality of life is a broader concept than economic production and living standards. It includes the full range of factors that influences what we value in living, reaching beyond its material standards”.

They suggest that indicators that go beyond being measures of income, wealth and consumption, and incorporate the non-monetary aspects of life, have an important role to play. These non-monetary aspects of life are defined by them as “Quality of Life”. To emphasise the importance of QoL, they recommend its use alongside with economic indices such as Gross Domestic Product (GDP) or income per capita.

Interest in Quality of Life emanates from the idea that patients want to live, not just to survive (McDowell, 2006). Quality of Life is a concept distinct from health, although in many ways is related to it (Wilson and Cleary, 1995). The concept of QoL incorporates all aspects of an individual’s existence (Torrance, 1987). These aspects might be health, education, housing, income, culture freedom, and perceptions of immediate environment (Bowling, 1995a:3; Guyatt *et. al.* 1993).

The health part of QoL, the so called Health-Related Quality of life (HRQoL) might be seen as the highest level of health outcomes, which start with biological and physiological factors and continue with symptoms, functional states, general health perceptions ending up to quality of life (Wilson and Cleary, 1995). Moreover, there is an increasing acceptance in the scientific community that QoL should be assessed when evaluating the outcome of a medical intervention (Bowling, 1996). The

growing interest in QoL measurement is best given by Gill and Feinstein (1994) who commented that:

“Since the 1970’s, the measurement of quality of life has grown from a small cottage industry to a large academic enterprise”.

QoL in general can incorporate a wide range of perceptions, experiences or states in many different domains. It can contain notions or domains of a psychological, cultural, interpersonal, spiritual, financial, political, temporal or philosophical nature (Calman, 1987).

3.2 The evolution of the concept

Although the term Quality of Life first appears in literature in the 20th century early approaches to notions similar to QoL appear in the work of Ancient Greek philosophers, especially Aristotle (Aristotle 384-322 BC; Patrick and Erickson, 1993; Fayers and Machin 2007). In his Nicomachean Ethics Aristotle used the word “*ευδαιμονία*” (eudaimonia), which is equivalent to “well-being” (despite the fact that by most writers, following Rackham’s translation (1868-1944), the term is rendered as “happiness”). The two concepts have been used interchangeably, although they are distinct since well-being is a broader concept than happiness (Deci and Ryan, 2008), as it contains more dimensions such as life satisfaction, morale, self-esteem and sense of coherence (Bowling 2005c). Aristotle’s perception of eudaimonia is considered to be the foundation of what later was called *perfectionism* (Sandoe, 1999).

It was not until the late 18th early 19th Century that the concept appeared again in the work of the English philosopher Jeremy Bentham (1748 – 1832). The founder of utilitarianism used the term “*well-being*”, which he defined as “*the excess of pleasure over pain*” and made qualitative and quantitative proposals for its measurement (Bentham, 1834). Along the lines of Aristotle he considers well-being as a concept that man should pursue in life and not as God’s gift. Bentham himself explains that this is the reason why his analysis is included in his book called Deontology. (*Deon* means that which is proper and *logia* means knowledge) [Bentham, 1834]. Bentham

considered *well-being* a more suitable term than *happiness* because he thought that happiness:

“...represents pleasure in too elevated a shape; it seems associated with the idea of enjoyment in its superlative degree” (ibid).

The opposite of well-being is ill-being. He also proposed that these measurements should be based on the subjective evaluations and concerns of those directly involved (Bentham, 1834). Bentham’s views on well-being are in some respect narrower than Aristotle’s, as he restricts the notion to the boundaries between pain and pleasure (Nussbaum, 2004). This perception might be influenced by the not so accurate Epicurean definition of happiness, which equates happiness with the combination of two states: that of tranquillity (*ataraxia*) and the absence of bodily pain (Bergsma *et al.* 2008). Another very important issue in Bentham’s work is the concept of “need”. Without the basic “needs” well-being becomes ill-being (Collard, 2006). Bentham’s theory of QoL, as seeking the enjoyment of pleasure and the avoidance of pain, has been classified in literature as *hedonism* (Sandoe, 1999).

These early philosophical approaches have in later years influenced some traditional social sciences approaches to quality of life. Although conceptually different from QoL, notions such as “happiness”, “good life”, “social well-being”, “life satisfaction”, or “morale” have been used as the basis of these QoL models (Bowling, 2005e). The first attempts to assess ‘level-of-living’ of families in the USA can be traced back to 1918. The attempts continued throughout the next two decades with sociologists such as McKain and Cottam trying to develop the idea of a “social report” and “level-of-living measures”. In 1942 Cottam and Mangus described the components of ‘standard of living’ as level of living, social participation, and social adjustment, concepts that come close to QoL (Sirgy *et al.* 2006).

Research on QoL started in the 1960s. The report of the President’s Commission on National Goals in 1960, and President Johnson in 1964, declared that goals can only be measured in terms of the quality of lives that people lead. In 1967 J.K. Galbraith stated that *“What counts is not the quantity of our goods but the quality of life”*. Bauer’s work on social indicators in 1966 and NASA’s reports on the nature and magnitude of secondary effects of the space programs gave impetus to QoL as a

separate field of research. The work of Bauer (1967) on 'social indicators' was the foundation of the social indicator movement which using statistical time series analyses tried to measure, evaluate, and forecast well-being and other conditions of society.

However, the turn of interest towards subjective indicators energized the domain of social indicators and measures of quality of life were introduced into sociological research in the 1970s and 1980s. In 1976, Campbell recognised the importance of personal responses to QoL issues, pointing out the limitations of statistical indicators and suggesting that economic - social indicators differ substantially from personal indicators of QoL (Campbell, 1976). With his associates they developed a lengthy questionnaire for measuring satisfaction with various domains of life (Campbell *et al.* 1976). The same year Liu developed a QoL index using objective indicators. QoL was defined as subjective satisfaction and, in terms of utility, as a political economy concept. The term QoL in sociological research appears around the end of the 1960s, and as late as 1979 in Sociological Abstracts (Schuessler and Fisher, 1985).

In 1976 a publication by Gerson attempted to conceptualise QoL using health-related quality of life as an example (Gerson, 1976). He argued that in a condition of chronic illness or morbidity several factors, such as money (ability to meet patient's financial needs), time (time needed for disease management), sentiment (losses and gains in respect, affection, self-esteem), and skill (self-administration of the disease) contribute to the quality of life of the patient. This approach, he argued: '*is capable of framing and answering questions about quality of life in any social situation*' (ibid). Since then QoL has become a main theme in sociological research and it is the issue where: '*the concerns of sociology and medicine converge*' (Levine, 1987).

3.3 Models of QoL

The term Quality of Life is an elusive and to a great extent vague concept, lacking conceptual clarity. It is a multi-level and amorphous concept for which there is no

consensus definition (Brown *et al.*, 2004; Bowling, 1995a; Bowling *et al.* 2003).It has been said that “*quality of life is easy to understand, but hard to define*” (Voruganti, 2008).

There is no consensus on a definition or measurement of quality of life. The establishment of an accepted theoretical framework for the concept would help its consistency and coherence as a health outcome. It would also help as a tool for monitoring and analysing quality of life in changing social structures (Noll, 2002). A model of QoL should give a representation or description of the concept, try to identify its constituents and predictors as well as give concrete answers to the problem of measurement. However, the nature of QoL *per se* makes this task essential because

“QoL is a multi-level and amorphous concept which reflects both macro societal and socio-demographic influences and also micro concerns, such as individuals’ experiences, circumstances, health, social well-being, values, perceptions, and psychology” (Bowling *et al.* 2003).

Nevertheless, there is not any consistent quality of life model. A number of theories have been proposed using different attributes of QoL in order to explain this complex phenomenon. Any attempt to taxonomise these theories and models proposed might be considered, according to Cummin’s phrase (1996), as “an attempt to order chaos”.

Bowling created a comprehensive list of models, by grouping together various theories that have been proposed and dividing them into nine main categories (Brown *et al.* 2004; Bowling, 2005e).). These categories, which will be discussed in some detail, are:

- objective indicators;
- subjective indicators;
- satisfaction of human needs;
- psychological models;
- health and functioning models;
- social health, social networks, support and activities;
- social cohesion and social capital;

- environmental models;
- idiographic approaches.

3.3.1 Objective indicators

The objective indicators usually include areas such as health, income, standard of living, housing, education etc. These factors have been proposed by researchers as constituents of quality of life and they are focused on measuring “hard” facts (Veenhoven, 2002). Objective indicators have the advantage of collecting data relatively easy.

Objective indicators might be of a demographic, economic, or epidemiological nature. Socioeconomic status and health (as indicated by morbidity or mortality and not by subjective health status) are two indicators used as objective predictors of QoL. There are correlations between them and one indicator determines the level of another, affecting the quality of life. In most cases these mechanisms have not been explained but the association is well established. However there is strong evidence that the two are consistently associated, although the mechanisms, causality and the complexity of this association have not been determined (Adler *et al.* 1994).

Gender also has an influence on QoL both in a direct and indirect way: direct, due to the injustice women face in society that affects their QoL (Annas, 1993); indirect through health related quality of life, where women almost in all cases experience higher morbidity, more extensive use of health care (Kandrack *et al.* 1991, less treatment satisfaction, and greater likelihood of developing depression due to the presence of a clinical disorder (Rubin and Peyrot, 1999; 1998; Unden *et al.* 2008). Age is another factor that plays an important role in determining the level of QoL for old people in general (Bowling, 2005e) or people having a health problem like diabetes (Brown *et al.* 2004).

Social indicators are a variant of objective indicators. A social indicator was meant to be a direct measure of welfare and it was a statistic of direct normative interest,

which facilitated judgements about a major aspect of society (Schneider, 1976). They have been used to detect changes over time, to monitor the social system, to evaluate interventions, and to forecast the future (Sirgy *et al.* 2006). Objective indicators could represent social, economic and environmental conditions as represented in the System of National Accounts, developed in the 1960s. This was based on the view that social monitoring should be expanded beyond traditional economic indicators and seeing output in terms of individual living conditions. The “institutionalisation” of social indicators (public recognition, political influence and participation in decision making) did not succeed and they eventually were abandoned (Hagerty *et al.* 2002).

However, the sole use of objective indicators might result to misleading conclusions. Objective indicators have not been very successful in predicting quality of life because they are focused only on external factors and conditions that researchers thought constitute QoL. Although there were statistical relationships between demographic and socioeconomic factors and QoL, these relationships were proved to be weak (Day and Jankey, 1996). It is now widely accepted that QoL is more than the objective conditions in which people live and that QoL is of a highly subjective nature i.e. it is what the respondent perceives it is.

3.3.2 Subjective indicators

Subjective or experiential indicators are those which involve some sort of evaluation by a person concerning some aspect or condition of his/her life (Brown *et al.* 2004). There are concepts such as well-being, happiness, or quality of life that cannot be fully understood without asking people how they experience and perceive the condition. It has been established that quality of life is mainly a subjective perception of life and that the features affecting it relies on value judgements rather than objective observations. Thus, the evaluations performed by people of concepts concerning their lives as their experience them are institutionalised or formalised by subjective indicators (*ibid*).

Criticism of subjective indicators has mainly focused on their comparability, validity and reliability. The first concerns the limited capability of subjective indicators to compare the conditions of different persons, cultures, or changing standards over time (Veenhoven, 2002). Validity questions arise because there is a possibility for a respondent to understand questions differently from what the investigator has in mind, while doubts about reliability arise due to lack of precision of the responses, as well as various distortions such as social desirability bias or other cultural biases (*ibid*). However, Veenhoven argued that objective indicators can only provide part of the information required, and focus on details rather than on the whole (*ibid*).

3.3.2.1 Objective versus subjective indicators

Measurements based on objective indicators could be seen mostly as mechanical methods, involving no human judgement and based mainly on laboratory tests. Objective indicators are what Campbell *et al.* (1976) called ‘harder’ than most subjective measurements, and are therefore more reliable. When human measurements are involved for an objective indicator, these are performed by external observers and are based on explicit criteria (Veenhoven, 2002). In this case, it is important to note that the distinction between objective and subjective indicators is not only a distinction between observers. A measurement is not subjective because it is performed by the patient or objective because it is performed by a third person e.g. a health professional. It is the measurement perspective that matters and not the person performing the measurement. As Mor and Guadagnoli (1988) argued: “*Objectivity is not bestowed upon a measure merely because another person makes it*”. Subjective measurements on the other hand are results of personal value-judgements, made by the people concerned, which are used as health outcomes (McDowell, 2006).

Proponents of objective indicators argue that these indicators are necessary because they give truer and clearer answers to the questions asked, whilst subjective indicators lack adequate clarity and quantitative strength. This reasoning might be true when the measurement concerns issues what Feinstein has called “paraclinical

data” such as a laboratory test, a pathology report, an expert’s opinion based on clinical indicators, etc. However, although objective indicators can be assessed independently of the patient’s evaluation, Hollandsworth (1988) proposed that objective criteria may relate more to the ‘quantity’ of life than its ‘quality’.

In health, subjective appraisals not only lack clarity, but they might be objectively wrong. According to Veenhoven (2002), this is the “*doctor knows best*” argument. However, there are conditions where doctors do not succeed in identifying the aspects of disease that are important to the individual patient. Also, it is sometimes difficult for patients to explain or describe to a doctor the feeling and the experience of a condition such as pain for example. As Virginia Woolf (2008) wrote in 1926:

“English, which can express the thoughts of Hamlet and the tragedy of Lear, has no words for the shiver and the headache... The merest schoolgirl, when she falls in love, has Shakespeare or Keats to speak her mind for her; but let a sufferer try to describe a pain in his head to a doctor and language at once runs dry”.

Furthermore, an objective indicator could be sufficient in assessing performance (for example the “ability” to perform a task), but there are assessments that need to measure concepts like the “capacity” to perform a task. Capacity cannot be measured by objective indicators or a third person, a health professional for example, as it requires value judgements by the respondent. Thus it is a subjective estimate and the only person who can assess it is the patient.

As far as QoL is concerned, the relationship between the two categories of indicators is a complicated issue because the mechanisms that determine the level of quality of life have not been explained adequately enough. Veenhoven (2002) argued that there are cases where correlations between objective conditions and subjective appraisals are modest or weak.

However, in some cases these correlations do not exist at all. The relationship between quality of life and disease is neither linear nor simple and indicators of the two concepts appear sometimes to have a reciprocal relationship. Thus, patients with an objectively poor quality of life report levels of wellness that exceed even those of the general population (Evans, 1991; Carr and Higginson, 2001). This phenomenon

has been called the “paradox of well-being” (Brown *et. al.* 2004) or the “disability paradox” (Carr and Higginson, 2001). The paradox consists in the presence of subjective well-being despite objective difficulties that should predict unhappiness (Mroczek and Kolarz, 1998). This discrepancy could partially be explained by the expectations model of QoL. The experiences of a person who lives with a condition or disease change their expectations, and their quality of life as a whole (Carr *et. al.* 2001). The phenomenon is not new. In late 19th century Leon Tolstoy first noticed that:

There are no conditions of life to which a man cannot get accustomed, especially if he sees them accepted by everyone (Tolstoy, 1877 [2004]).

This change is also true when health conditions change, as most patients can adapt to the adverse life circumstances that occur after the appearance of a disease (Evans, 1991). The phenomenon is called “response shift” and poses certain problems to QoL measurement (Donaldson, 2005; Oort, 2005b). ‘Response shift’ involves recalibration of internal standards, reprioritisation of values, as well as reconceptualisation of quality of life ((Sprangers and Schwartz, 1999; Oort 2005a; Schwartz *et al.* 2007; Swartz, 2010). Although response shift has received a lot of attention, there is no adequate explanation of the phenomenon. Probably the explanation lies in other disciplines, such as philosophy, where suffering was considered by Nietzsche as a constituent of life: *“To live means to suffer, to survive is to find some meaning in the suffering”*.

Although suffering is not desirable Nietzsche believes that:

“when misfortune strikes us, we can overcome it either by removing its cause or else by changing the effect it has on our feelings, that is, by reinterpreting the misfortune as a good, whose benefit may only later become clear”(Nietzsche, 1886).

Lawton (1991) proposed that objective and subjective indicators of QoL should be used in parallel. Both of them are important for quality of life with objective measures providing *“an anchoring point from which individual perceptions may deviate”*. According to him (1999) the two types represent a continuum and a clear separation between objective and subjective indicators in QoL research is not always possible. For example, when the source of information is an individual, indicators

considered as objective, (e.g. income or education), could encompass subjective biases.

Stiglitz *et al.* (2009) in their report support the combined use of objective and subjective indicators arguing that:

“There is a consensus that quality of life depends on people’s health and education, their everyday activities (which include the right to a decent job and housing), their participation in the political process, the social and natural environment in which they live, and the factors shaping their personal and economic security. Measuring all these features requires both objective and subjective data”.

The current trend among investigators is to use both types of indicators. However, the choice of some particular objective indicators requires knowledge of people’s values and how these indicators influence them (Diener and Suh, 1997). Also, the interrelationships between the two types of indicators should be taken into consideration because not only they affect the assessment of QoL but they can also influence the choice of the measuring indicator *per se*.

Finally, it should be noted that even the combined use of the two types of indicators does not provide a conclusive answer to QoL assessment. QoL should be considered as *“a multidimensional collection of objective and subjective areas of life, the parts of which can affect each other as well as the sum”* (Bowling and Gabriel, 2004). Nevertheless, both types of indicators are not sufficient in explaining this “sum”, despite the fact that they affect it. In a survey published by Bowling and Windsor (2001) searching for subjective and objective predictors of quality of life, the objective indicators (12 socio-demographic + a health status indicator) accounted for only 5% of the variation of the total ratings. When subjective indicators were included in the model (six variables) the variance explained was only 16% of the total. While subjective indicators explained more variance than the objective ones (11%) the total was still very low, highlighting the complexity of the quality of life concept and leaving the question of measuring it unanswered. Therefore, the discussion about the relative importance of the two types of indicators or the relationship between them is only part of the problem of QoL assessment and provides no answers to the problem of QoL measurement.

3.3.3 Satisfaction of human needs

The concept of *need*, first introduced by Bentham [1834], reappears in contemporary quality of life literature. The *needs* approach relates QoL to the ability and capacity of patients to satisfy certain human needs. This approach is based on Maslow's hierarchy of basic human needs, which claims that there is a general pattern of needs that people try to satisfy in the same sequence. This pattern consists of five categories or levels of needs arranged in a structure in which the appearance of one need usually rests on the prior satisfaction of another. He called this hierarchy "prepotency". These needs are: The "physiological" needs, safety needs, love needs, esteem needs, and the need for self-actualisation (Maslow, 1943). Needs, according to Veenhoven (1991), are neither arbitrary demands nor can they be arbitrarily adjusted. To the contrary, they are given requirements for functioning, inherent to the human organism.

Human needs have been used as theoretical basis for the development of quality of life measures especially for people with mental health problems (Hunt and McKenna, 1992; Bigelow *et al.* 1991). Fayers and Machin (2007) argued that the level of quality of life depends upon the degree of fulfilment of basic needs that include aspects such as employment, food, sleep, mobility, identity, self-esteem, affection, love, security, shelter, and pain avoidance. However, this view could be considered as a general one because basic needs differ among people or societies. In the developed countries especially, satisfaction of basic needs is far from considered as being a feature of quality of life.

3.3.4 Psychological models

This general heading covers various concepts that have been used as QoL proxy variables. These concepts are conceptually distinct from quality of life, despite the fact that they overlap and are sometimes used interchangeably (Bowling 2005e). These are:

- The concept of subjective well-being includes aspects such as moods and emotions (affect) as well as overall life satisfaction. Well-being according to Diener has three characteristics. It is subjective, it includes positive factors and not just negative as most of the measures of mental health, and it is usually measured by global assessments of all aspects of a person's life (Diener, 1984; Diener *et al.* 1999);
- Life satisfaction, which is the result of an assessment of one's overall life compared with an appropriate standard (Diener *et al.* 1985, cited by Brown *et al.* 2004);
- Happiness, which according to Veenhoven (1989) is: "*the degree to which an individual judges the overall quality of his life as a whole favourably*". Health has been considered as the main predictor of well-being (Hayes and Ross, 1986), satisfaction with life as a whole, satisfaction with quality of life, and general happiness (Michalos *et al.*, 2000). However, the relationship between health and happiness is not unidirectional at least at the prevention level. Happiness protects physical health and according to Veenhoven (2008) although it "*does not cure illness it does protect against becoming ill*";
- Morale, which is a mental state that encompasses concepts like confidence, cheerfulness, enthusiasm, willingness to perform a task or respond to a problem. Also discipline and loyalty to a cause are sometimes included in this multi-defined and thus undefined concept;
- Self-esteem and self-concept. Self-esteem according to Maslow (1943) is a basic human need. It could be described as one's self-image and refers to how much value people place on themselves (Baumeister *et al.* 2003). Self-esteem has a strong relation to happiness, although the causation has not being established, as well as overall physical health (*ibid*). Self-concept could be seen as the whole of self-related beliefs that emerge from different aspects or domains of life and it may be described as evolving within a context of associations and configurations with objects, persons, and other concepts (Ziller, 1974);

- Social comparisons and expectations theory. According to this model QoL is the discrepancy between desired and attained goals (Calman, 1984; Bergner, 1989). By narrowing the gap between expectations and reality QoL is improving. Michalos (1985) argued that there are seven types of discrepancies and classified them as not-attained goals, keeping the attained goals (i.e. with the present situation as constant. The seven types of gaps exist between: a) What one has and what wants b) What one has and relevant others have c) What one has and the best ever had in the past d) What one has and what one deserves e) What one has and what one is expected to have at a certain point of time in the past f) What one has and what one needs g) What one has and expects to have in the future;
- Optimism and pessimism. Optimism and its opposite pessimism are personality constructs that may have important implications for the manner in which people deal with the stresses of life (Scheier *et al.* 1989). Optimists differ from pessimists in the manner in which they cope with serious disease or specific health threats (Scheier *et al.* 1994);
- Self efficacy, self-mastery, autonomy and control. The first two concepts refer to one's competency or capability in succeeding an intended goal. As optimism, they are also personality constructs. (Brown *et al.* 2004). Autonomy and control encompass the notions of independence (freedom from control), and autonomy (the freedom for self-determination). Autonomy is a basic human need and it is a distinct notion from independence. The differences between the two concepts and their relation to diabetes will be discussed in Chapter 9 of this thesis, where semantic equivalence is discussed;

3.3.5 Health and functioning models

Health status is in theory and through empirical evidence related to Quality of life by its subset, Health Related Quality of Life (HRQoL). The concept of HRQoL has also been related to functional status, either physical or social. However, the two

concepts are different in nature. Also, their association as well as the direction of this association are still controversial. The lack of agreement among writers on these issues is reflected in the multiplicity of measures proposed for the assessment of the concepts. The various types of measures are discussed further in this chapter.

3.3.6 Social health, social networks, support and activities

There is strong evidence emerging that the above concepts affect QoL each one in its own way and capacity. Social health has been defined as: “*the social support system that might intervene and modify the effect of the environment and stress on both mental and physical health*” (Bowling 2005e). The notion of social networks refers to: “*the social relationships that surround a person, their characteristics and individuals’ perceptions and valuations of them*” (*ibid*). There is no agreement on a precise definition of social support, but in general terms is the aid, (emotional, instrumental, or financial) network members might get from each other. There is evidence however, relating social support with physical and mental health (Cohen, 1988). The way that concepts such as social networks and support are connected to QoL is still a matter of research and the type of their association (direct or indirect) remains controversial.

3.3.7 Social cohesion and social capital

The concept of social cohesion is based on the principle that individuals are influenced both by external societal forces as well as internal personal factors. There is no agreement on a definition of the concept, but in general terms it could be described as all that which brings people together. It refers to ideas like community participation, reciprocity, social relationships and social bonds. Chan *et al.* (2006) defined social cohesion as:

“A state of affairs concerning both the vertical and the horizontal interactions among members of society as characterised by a set of attitudes and norms that includes trust, a sense of belonging and the willingness to participate and help, as well as their behavioural manifestations”.

Although the definition of the concept is still controversial there is a general consensus on the features that a cohesive community should have. The characteristics of a cohesive community, according to the British Government, is one where there is a common vision and a sense of belonging; the diversity of people is appreciated and positively valued; people from different backgrounds have similar life opportunities; and strong and positive relationships are developed between people from different backgrounds in the workplace, schools and neighbourhoods (Home Office, 2002). Social cohesion is an important feature of every society and should be considered as a ‘social value’ depending on culture and other socioeconomic factors (Chan *et al.* 2006). Social cohesion, in relation to social capital, is a more holistic concept affecting society in general and not individuals. In this sense it is possible for a society to maintain a high level of social capital but have no social cohesion (e.g. segregated societies).

Social capital is a different to social cohesion concept. According to Putnam (1993) it refers to: *“features of social organisation, such as networks, norms, and trust that facilitate coordination and cooperation for mutual benefit”*. Social capital should be considered as a subset of the concept of social cohesion and refers to the opportunities offered to individuals by communities and social networks to: *“act together more effectively to pursue shared objectives”* (Putnam, 1995). The definition of social capital is a highly controversial issue (Szreter and Woolcock 2004a; Putnam, 2004), but most definitions are in some respect overlapping (De Silva *et al.* 2005; Szreter and Woolcock, 2004b).

There is also some conceptual disagreement between social capital and support. Walkup (2003) suggested that social capital is connected with the supportive relationships among individuals. This is related rather to social support than social capital, which is an attribute of a society or a group (McKenzie, 2003). Social capital should be considered as a “public good” (Putnam, 1993), because unlike conventional capital it is not the private property of the people who benefit from it.

Putnam's view however, does not mean that social capital is something material because it is a term describing a variety of social processes (McKenzie, 2003). Finally, it has been suggested that social capital is related to self-rated health, physical, and mental health, although the mechanisms of this linking have not been adequately explained (Kawachi *et al.* 1999; DoH, 2001; Kawachi and Berkman, 2001; Hawe and Shiell, 2000).

3.3.8 Environmental models

Environment, according to the WHOQOL, constitutes one of the six broad domains of quality of life. It is so important that the other five domains (physical and psychological domains, independence, social relationships and beliefs) although independent from each other are also seen in relation to: “*salient features of the environment*” (WHOQOL, 1995). Environmental factors affect both the pathogenesis as well as the treatment of a disease. Objective environmental factors such as water and air quality, pollution of any kind, nutrition, lack of physical mobility, are some of the factors considered responsible for the onset of a disease. Lawton (1983) argued that some environmental features are directly relevant to QoL. He differentiates between “*Objective environment*” which is everything that “*lies outside the individual and is capable of being counted.... by observers other than the subjects*” and the “*environment as perceived by a person (which) ... is a domain of perceived quality of life*”.

There are only a few studies trying to identify environmental factors influencing QoL of diabetes patients. However, family environment, dependence on spouses, neighbourhood characteristics or problems, as well as new technologies concerning treatment regimens are determinants for complications, competence and diabetes management, which are directly related to QoL (Gary *et al.* 2008; Maddigan *et al.* 2006; Trief *et al.* 1998).

3.3.9 Idiographic approaches.

These approaches are based on the fact that each person is an individual, living in a particular environment to which general rules or universal principles cannot be applied. This perspective is called phenomenological and its central issue is that QoL cannot be assessed by group analyses as the concept is focused on perceptions of the individual or on what Ziller (1974) calls the views of the ‘experiencer’.

The individualised approach to QoL therefore begins with the perspective that “*QoL is what the individual says it is*” (Joyce, 1994). When lay people’s views are not been taken into consideration for the construction of a questionnaire, the items reflect the “culture” of the developers and not that of the respondents (Fox-Rushby and Parker, 1995; Bowling, 2005e). Also, a measure should be sensitive to differing values people place on various aspects of their lives, as well as to different priorities they set relatively to these values (Bowling, 2005b).

By approaching QoL through pre-defined constituents, for example according to the WHO definition, there is the possibility that domains important to people to be excluded from the analysis. An individual should be allowed to identify the concepts of quality of life that are important to him/her, indicate their relative importance and then be asked to evaluate QoL according to these concepts (McGee *et al.* 1991).

Mc Dowell (2006) argued that translation and cultural adaptation of an instrument into another language is in essence an idiographic approach. This view seems self-contradictory as the word “idiographic” describes the study of the individual (Greek: *idio*) and does not allow a macro approach to a concept, unless a language or a nation, compared with another, might be considered as an individual entity and treated as such.

3.3.10 Conclusion

The taxonomy of quality of life models highlights the complexity of the concept. Each model approaches quality of life from a different perspective, based on what their proponents consider underpins quality of life. This is the only characteristic that these models have in common. At the same time it could be considered as their common weakness. All of them have been based on expert opinion rather than on lay people's judgements about their quality of life (Walker and Lowenstein, 2009). Therefore:

“Investigation of lay views is essential if the current body of knowledge on the constituents of this complex concept is to be developed, if measurement scales are to have any relevance to people and their everyday lives, and if public policies which affect life quality thereby influenced” (Bowling *et al.* 2003).

3.4 Towards a definition of QoL

There is a plethora of definitions with conceptual differences among them concerning the real meaning of the term and the topics it covers. Thus, there is no widely accepted definition, but in general terms quality of life should be conceived as a grade of “goodness” (Bowling, 2005c).

The lack of a consensus definition has its origins, as mentioned above, in the disagreement among scientists about the theoretical framework of the concept. The lack of agreement and the differences in definitions of quality of life have created doubts even for the value of the concept *per se*. Rapley (2003), asked the question: *“should we hang up quality of life as a hopeless term?”*, responding that the concept can be useful only if we consider it as a *‘sensitising concept’* for approaching issues like service provision, or the question of how ill people live, rather than as a *‘formalised, psychometric, conceptual framework’* (*ibid*).

The variety of definitions has been demonstrated by Farquhar. In 1995 she proposed a taxonomy classifying the various definitions of QoL into four categories:

- Global definitions: All encompassing, usually incorporating notions such as satisfaction and happiness. They are too general (indicating little about the components of QoL) and too non-specific to be used on their own;
- Component definitions: They break down QoL into components or dimensions. They operationalize the concept of QoL better than global definitions and can identify certain characteristics essential to any evaluation;
- Focused definitions: They refer only to a small number of QoL dimensions (e.g. health/functional ability);
- Combination definitions: They are global definitions combined with components of QoL (Farquhar 1995).

However, despite the disagreement on definition, there is some degree of consensus about three characteristics of QoL (WHOQOL 1995):

- Quality of life is subjective;
- It is of a multidimensional nature and;
- It includes both positive and negative dimensions.

Almost all investigators agree on the first feature of QoL. This belief is rather based on the acceptance that health as a construct exists as some perceptual property of patients, i.e. health is a percept (Hyland 1993).

As far as the second characteristic is concerned, the vast majority of investigators, with some exceptions, such as, Beckie and Hayduk (1997), agree on the multidimensionality feature of QoL. Beckie and Hayduk (1997) investigating the dimensionality, globality and domain specificity of QoL, considered QoL: “*as a global personal assessment*”, and concluded that QoL was: “*a unidimensional concept despite the multiplicity, diversity, and complexity of its causes*”.

The World Health Organization QoL Group (WHO, 1995) argued that quality of life is of a multi-dimensional nature and includes at least three dimensions on which there is a high degree of a consensual agreement:

- *Physical* i.e. individuals' perception of their physical state;
- *Psychological* i.e. individuals' perception of their cognitive and affective state;
- *Social* i.e. individuals' perception of the interpersonal relationships and social roles in their life.

It also adds a fourth dimension, the *spiritual*, which it defines as the individual's perception of *meaning in life* (WHO, 1995).

Taking into consideration the characteristics and dimensions mentioned above, the World Health Organization defined quality of life as:

"... individuals' perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals expectations, standards and concerns. It is a broad-ranging concept incorporating in a complex way individuals' physical health, psychological state, level of independence , social relationships, personal beliefs, and their relationships to salient features of the environment" (WHOQOL Group, 1995).

Others have deduced definitions by referring to the factors influencing quality of life. Thus, the majority of definitions are based on attempts to break-down the QoL construct into constituent domains. However, neither the variety nor the number of domains that should be included in a definition has been agreed. Such an attempt has been characterised by Cummins (1996) as: *"an attempt to order chaos"*.

Bergner (1989) argued that certain dimensions should be taken into consideration when one is trying to define quality of life. These dimensions are: physical activity, social and leisure activity, work, symptoms, loss of income, cognition, emotional adaptation, self-esteem, anxiety, stress, sexual activity, interpersonal relationships, impotence, incontinence, and overall satisfaction with life.

The above problems have led to a situation where investigators do not provide a definition of QoL in their reports, or even justify their selection of quality of life measures (Haas, 1999). Others adopt implicit, narrow or discipline-bound perspective of quality of life (Bowling and Gabriel 2007). Evaluating 75 articles Gill and Feinstein (1994) discovered that only 11 (15%) conceptually defined QoL, 35

(47%) identified the targeted domains, and only 27 (36%) explained their selection of the chosen QoL measure.

McDowell (2006) supported that investigators leave the term of QoL undefined when they want to have the freedom to select whichever indicator they wish. Others limit their definitions to components of QoL which they see as the whole concept (Farquhar, 1995). Along the same line Bradley (1996) argued that the meanings which are given by investigators to QoL differ from one another and in many cases it is one that fits their own work. Thus:

“...the term (QoL) is used without definition though a remarkably wide range of meanings is implied by the choice of instruments used to measure quality of life. Just as psychologists often resort to defining intelligence as ‘that which intelligence tests measure’, so too quality of life may be defined as ‘that which quality of life instruments measure’”.

However, this *post hoc* approach in defining QoL is a fallacy “brush under the carpet” approach and not a definition based on theory or practical experience. There is a need to find the exact constituents of the concept that is a definition on which the study should be based. As Sen (1993) stated:

“If an underlying idea has an essential ambiguity, a precise formulation of that idea must try to capture that ambiguity rather than hide or eliminate it”.

3.5 Theoretical – Operational Definitions

The disparities between theory and real life subjective judgements go back to Aristotle ([384-322] 1975)) who first correctly identified the differences between the judgements of “wise-men” and of “lay people” (Joyce 1994). Along the same logic Nietzsche declared in Zarathustra that “*there is more wisdom in your body than in the deepest philosophy*” (Nietzsche, 1887).

Discussing the role of theory and conceptual models within population health research Carpiano and Daley (2006) state that: “*Theory is a necessity*” (their italics). They define “theory” as the:

“Logically related propositions that aim to explain and predict a fairly general set of phenomena” (ibid).

However, the controversy over theoretical and operational definition models does not aim to repudiate the value of theory in conceptualising or explaining phenomena. Popay (2006) distinguished academic theories used in research and the ones developed in ordinary life by lay people. The former theories are: “*multifactorial involving the addition of more and more variables into putative models*”. In contrast to these:

“*...the theories we all develop as lay people as we seek to make sense of our experience of health and illness are interpretations and elaborations of the meaning of causal factors in the context of everyday life*” (ibid.).

She further argued that lay theories represent a challenge to the objectivity of expert theories as well as to the authority of professionals to determine the way in which problems are defined. Thus, she concluded, lay theories represent a scientific as well as a political challenge to the institutional power of expert theories (ibid).

In practice, as far as research for quality of life of an individual or a population is concerned Bowling (2005e) argued that although the division of QoL into predefined individual components helps measurement, it may not tap people’s subjective perceptions of QoL. Evaluations of QoL should evolve from the person whose life quality is assessed and in Merleau-Ponty’s (1962) terms is the ‘perceivable perceiver’. What should matter most therefore, are the people’s beliefs about their own quality of life or as Joyce (1994) stated that “*quality of life is what the patient says it is*”. Nevertheless, the problem of disparity between theory and experience, according to Joyce, still besets the study of QoL.

Having accepted that quality of life is a subjective individualistic perception of a patient’s values about life, the fact that there are common values among people within a society concerning what constitutes a good life or quality of life should be ignored. A definition based on the values that people assign to the notion of quality of life, as these emerge from various research would be most representative, operational, and reliable. Bowling (2005c) proposed that:

“*most people define their quality of life in terms of having a positive psychological outlook and emotional well-being, having good physical and mental health and the physical ability to do the things they want to do, having good relationships with*

friends and family, participating in social activities and recreation, living in a safe neighbourhood with good facilities and services, having enough money and being independent”.

This definition embraces to a great extent the important factors influencing quality of life and seems to be operationally and functionally suitable to be used as a guide for the final choice of measure for this research. However, by accepting this definition the problem could not be considered as solved, because this research has to compare quality of life between groups of patients with different socioeconomic background and residence. This represents an additional difficulty and raises questions on whether the QoL of a farmer for example differs from that of a city dweller or that of a housewife and a businessman with similar illness (Schipper, 1983). It seems that there is not a simple answer to this question. Priorities and notions that concern quality of life differ among groups of society. Bowling presented evidence that young people seem to prioritize finance and employment whilst older people prioritize the ability to get out (Bowling *et. al.*, 2003). Differences do not exist only among young and old people. Although adults within a community share a basic core of values, irrespective of their age, social, cultural and demographic strata, they tend to prioritize these values differently. Thus, QoL measures should be sensitive in detecting these differences (Bowling, 2005e).

Chapter 4: Health and Health Related Quality of Life

4.1 Health

Health has been defined by the World Health Organization (WHO, 1952) as:

“A state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity”.

This definition has the advantage of focusing on the positive aspect of health and not the negative one by its absence during disease or illness. Positive health could be considered as:

“the ability to cope with stressful situations, the maintenance of a strong social-support system, integration in the community, high morale and life satisfaction, psychological well-being and even levels of fitness as well as physical health” (Bowling, 2005c).

The concept of positive health is important because it has been used by many writers in trying to define concepts such as quality of life or even in their attempt to link the broad concept of health to QoL.

Nevertheless, the WHO definition has some disadvantages. It is a definition of a utopian nature (Bowling, 2005c: 4) and at the same time its concepts suffer from a lack of clarity. Criticism has been concentrated mainly on three issues:

- The definition identifies three dimensions of health namely physical, mental and social. It does not include physiologic health i.e. the status and functioning of specific organ systems. This fourth dimension was introduced later by Brook *et al.* (1979).
- The WHO definition does not delineate which state of well-being is healthier than others (Patrick and Erickson, 1993).
- Also, it is not clear whether the term social well-being refers to socioeconomic environment in general or to social integration and social interaction (*ibid*).

Despite its utopian nature and the above disadvantages the WHO definition encompasses meanings that are used in other health related concepts and provides a basis for defining health status, quality of life, morbidity, or well-being. Thus, a

plethora of health related measures have been created which are not based on demographic or epidemiological indicators only, but contain the concepts of physical, mental, and social well-being introduced as health domains by this definition (Bowling, 2005e).

4.2 Health Related Quality of Life

Health Related Quality of Life (HRQoL) has its origins in the concept of positive health, and is not defined simply as the absence of disease, but it has a positive dimension. Physical, mental, social well-being, functioning, ability to cope, adjustment and efficiency of mind and body are some of the conditions embodied in positive health and constitute parts of the concept health-related quality of life (Bowling, 1995a).

By having defined QoL as a grade of “goodness”, HRQoL should be seen as the “goodness” of the aspects that might be affected by health. Thus, HRQoL is a distinct concept and it represents only one dimension of the wider QoL (Bowling, 2005c). Also, the scope of HRQoL is of a more limited nature and it is usually used to assess health determinants and evaluate interventions.

There are no clear boundaries between QoL and HRQoL. This is because the other parameters mentioned above can affect a persons’ HRQoL. At the same time, the opposite is equally true. When a person is ill or diseased almost all domains of life are affected and may become health related (Guyatt *et. al.* 1993). This holistic approach to the nature of quality of life (Haas, 1999) has resulted to a situation for which the terms “Quality of Life” and “Health Related Quality of Life” are often used interchangeably in medical literature, despite the fact that they are distinct from one another.

Patrick and Erickson (1993), argued that:

“Health related quality of life is the value assigned by individuals, groups, or society to the duration of life as modified by the impairments, functional states, perceptions, and social opportunities that are influenced by disease, injury, treatment, or policy”.

This appears to be a sound definition of HRQOL because it encompasses five different aspects: One quantitative (duration) and four qualitative (impairments, functional states, perceptions, and opportunities). Therefore, according to this definition, HRQOL combines quantity and quality of life into a single value.

Finally, Polonsky (2000) introduced a distinction between HRQoL and disease-specific QoL. Focusing on diabetes-specific QoL and accepting the three dimensions of the WHOQOL definition, he argued that disease-specific QoL is a subset of overall HRQoL. Disease-specific HRQoL then refers to patient's sense of how the disease is compromising his well-being in physical, psychological and social functioning. He distinguished between two categories of distress caused by the disease: Intrinsic impairments (the perceived direct burden caused by the disease or some aspect of it); and attributional impairments (the perception of the disease as being responsible for distress in the three areas of functioning). He continued arguing that although other parameters of HRQoL, such as self-efficacy, coping style, treatment satisfaction, are very important variables and sometimes contributors to disease-specific QoL, they are not elements of the construct and cannot be considered synonymous to it. Thus, instruments should refer solely to patient's perception of how the disease affects the well-being in the three areas of physical, psychological and social functioning.

4.2.1 Health-Related Quality of Life – Health Status

Very often terms such as HRQoL health status, functional status, well-being and health related quality of life are used by writers with different and sometimes interchangeable meanings (Patrick and Bergner, 1990; Gill and Feinstein, 1994; Smith *et al* 1999; Speight, 2002). The extent of this phenomenon has led Gill to question whether QoL has in practice “*lost its distinctive or unique meaning*” (Gill, 1995). This is probably because a chronic disease does not affect quality of life only. When a patient is ill almost all aspects of life can be considered as health related

(Guyatt *et. al.*, 1993). Thus, the answer to the question “*what is or isn’t part of health*” (Patrick and Erickson, 1993) is still to a great extent inconclusive.

Bergner compared the use of these terms by reviewing papers abstracted from *Index Medicus*. She concluded that QoL, as used in clinical research, is a vague term without conceptual clarity. On the health status and QoL controversy she argued that: “*One of the striking differences between the notion of quality of life and that of health status is level of conceptualization. Quality of life as it is used in clinical research is a vague term without conceptual clarity. It is what investigators mean it to be*” (Bergner, 1989).

Moreover, as if the lack of conceptual clarity was not enough, there is also a problem regarding the direction of causality. Bergner argued that QoL was considered by people as a risk factor or cause of disease and at the same time as an outcome of medical care.

On the other hand health status:

“*...is clearly concerned with health and not with other aspects of life, many of which influence its quality*” (*ibid*).

The lack of clear distinction between the concepts of subjective health status and health-related quality of life could be attributed to the fact that both concepts are patient-based assessments. However, subjective health status is simply a self-reflecting assessment of health, while HRQoL refers to the impact of a perceived health state on an individual’s potential to live a subjectively fulfilling life (Bullinger *et al.* 1993).

Other writers believe that there is real no distinction between general health status measures and measures of HRQoL and if there is any it is that QoL is broader and extends to other topics (Mc Dowell, 2006). This view could be partly justified by taking into consideration the fact that the term health status is currently used as a multifaceted concept and overlaps with the broader concept of health-related quality of life. Nevertheless, health status is and should be considered as only one domain of HRQoL (Bowling, 2001), or as Lawton (1991) notes:

“*Self-rated health is an operationalization of the health domain of perceived quality of life*”.

Health status therefore and HRQoL, although related, are two different concepts and should be treated as such. Moreover, Bradley (2001) argued that the two notions not only differ in essence but sometimes act in an antagonistic way, as efforts to achieve a high level of health status may cause damage to QoL, especially when management of diabetes is concerned. Intensive treatment of diabetes with insulin for example, may lead to a higher health status but not necessarily to a better QoL. Bradley's argument might be reinforced by Glasgow *et al.* (1999), who state that there is a distinction between '*disease-oriented medicine*' and '*patient-oriented medicine*'. The first one aims at making the disease better. In the case of diabetes this is possible through a successful glycaemic control. The second kind of medicine achieves its aims if the patient is better, enjoying a higher quality of life. HRQoL measures are directed to '*patient-oriented medicine*' and their role is of great importance to this kind of care.

There is a wide consensus about the dimensions that the term health status covers. The five dimensions of health status are: Genetic foundation, biological, physiological, anatomical condition (disease state, disability or handicap state), functional condition (social role performance, physical performance, cognitive performance), mental condition (mood or feeling state, affective state), and health potential (longevity, functioning, disease & disability, disadvantage).

On the contrary, although QoL extends to other wider topics there is no consensus over the dimensions that should be included in the concept. Thus, tackling the definition problem of QoL becomes a complicated issue that needs a lot more attention. Despite the controversy, throughout this work a clear distinction will be made between the concepts of "Health Status" and "Quality of Life". This distinction is very important for this project and the two concepts are to be measured separately by two different instruments.

4.3 The Measurement of HRQoL

“Everything that can be counted does not necessarily count, everything that counts cannot necessarily be counted” (Albert Einstein 1879-1955)

4.3.1 Introduction

Measurement is the most important aspect in assessing a condition or an outcome. As Stiglitz and his associates (2009) stated:

“What we measure affects what we do; and if our measurements are flawed, decisions may be distorted”.

Measures of health, disease, and Health Related Quality of Life belong to the broad category of “subjective health assessment” or “patient-reported outcomes”. The need to measure these concepts occurred when evidence showed that objective test results, clinical measures and socio-demographic data suitable for a diagnosis were not enough to explain how a patient experiences illness or disease (Albrecht, 1994).

The measurement of medical outcomes methodologically is mainly based on the positivist approach. The core assumption of the positive approach is that social science is identical in logic with natural science and that its concepts can be explained in terms of cause and effect relationships, and measured with methods similar to the natural sciences. However, this approach has been criticised, especially during the last 40 years, as misleading because unlike natural science social theories are not about independent objects, but they are constituted by self-understanding that is the meanings that participants attach to them (Taylor, 1985). Also, positivism does not pay attention to the underlying mechanisms that determine these concepts. Another approach to health and disease measurements is the so-called phenomenologist approach, which is based on the idea that medical outcomes depend on individuals’ perceptions and not on predetermined measurement scales, which cannot capture the subjectivity of the individual. A third way to tackle the

measurement problem is of a more idiographic nature, trying to tap the values and measure the aspects that are unique to individual's life (Bowling, 1999).

4.3.2 The value of measuring HRQoL

The measurement of HRQoL has been defined as “*the level of health status filtered by individual health perceptions*” (Testa, 2000). This measurement definition tries to define HRQoL by combining the level of health status, (as expressed in terms of function, symptoms, emotion etc.) with the patients' perceptions of worry distress, well-being, satisfaction, expectations etc. This bidimensionality, according to Testa, gives an understanding of the forces that shape patient behaviour and their ability to adhere to diabetes treatment regimens.

There is a variety of opinion concerning the importance and use of HRQoL measurement and an analogous number of reasons has been proposed. Health-related quality of life is important for measuring the impact of chronic disease (Patrick and Erickson, 1993; Guyatt *et. al.* 1993). Bowling (2001) extends this view arguing that: “*HRQoL as an outcome measure broadens outcome towards considering the impact of the condition and its treatment on the person's emotional, physical and social functioning and lifestyle*”.

McDowell (2006) argued that quality of life measurement in health research provides a formal means for the patient's judgement to influence treatment. Guyatt and his associates give a comprehensive reasoning about the use of QoL measurements by arguing that these measurements can have three purposes. The first is discriminative that is to distinguish among individuals or groups, the second is predictive that is to classify individuals into a set of predefined categories, and third is evaluative i.e. to measure the magnitude of longitudinal change of an individual or group (Guyatt *et. al.*, 1993; Kirshner and Guyatt, 1985).

Higginson and Carr (2001) proposed that the measuring quality of life in clinical practice may have five different uses: a) identifying and prioritising problems; b) facilitating patients to communicate their problem; c) screening for any hidden

problems; d) facilitating shared clinical decision making; and e) monitoring changes or responses to treatment. Nevertheless, despite the value, significance and the variety of its uses, there is no widely accepted theory or instrument for the measurement of quality of life (Brown *et. al.*, 2004).

4.3.3 What is important in measuring HRQoL

There are three implicit assumptions in measuring quality of life: The first one is that we know what is to be measured, the second one is to understand why particular variables are measured, and the third is that the estimate is a valid indicator of overall quality of life (Lancet, 1995).

As far as the first assumption is concerned, that is the knowledge of what is to be measured, it is accepted that there is no consensus definition of quality of life. The lack of a gold standard instrument for measuring quality of life is attributed by Farquhar (1995) to this lack of definition. However, even by accepting that the domains described by the WHOQOL definition (physical, psychological, and social functioning) are necessary for measuring QoL, they are not sufficient to tackle the problem of subjectivity and lay perceptions of QoL (Bowling, 2005b).

This has implications concerning the second assumption that is why particular variables are measured. Quality of life as a concept extends over a wide range of topics and disciplines, therefore the mechanisms that determine people's perceptions and the choice of variables for measuring the concept will never be explained adequately enough. Instruments and the variables used to measure QoL are based on expert opinions rather than those of lay people and empirical evidence. This is against the widely accepted view that: "*the problems and priorities which are important are those of the individual and not of the observer*" (Calman 1984). The lack of empirical evidence results in the construction of measures that include items with little importance or relevance to people in everyday life (Brown *et. al.* 2004).

It is the importance of items that plays the significant role in relation to the third Lancet (1995) assumption, which is that the estimate is a valid indicator of overall quality of life. Importance in this case should be seen under two distinct perspectives: One of values and one of priorities. The first is based on the view that quality of life is a concept that invokes the notion of value (Patrick and Erickson, 1993). Values may differ among different societies. However, within a society people in general share a basic core of values. Various groups of any society (cultural, social, demographic etc.) have different priorities concerning these values. Importance in this case relates to emphasis or priority people place on these values (Bowling, 2005b). Thus, importance refers to the personal values as well as the priorities of the respondent.

Care should be taken in assuring that the measure is a valid and reliable indicator of what it purports to measure. However, the validity of an indicator depends largely on importance of items rather than multiplicity or variation. Measures that are not focused on domains or items that are important to the individual patient could not be valid or reliable. As Gill (1995) argued quality of life will be measured not just with statistical elegance, but only when investigators acknowledge the importance of patients' values and preferences.

Furthermore, there are some other factors referring to questionnaires and the mode of administration that should be taken into consideration in QoL measurements. Standardised instruments that use the same questioning and weighting for all respondents could create biasing influences and distort the results. In a study published by Bowling, different results were obtained depending on the method of questioning and coding. There were differences between the responses obtained when respondents chose a pre-coded show-card and the ones obtained from open coding of verbatim responses (Bowling, 1995b). In a later study Bowling suggested that results could also be influenced by the question order as well as response-choice available on a self-reported instrument (Bowling and Windsor, 2008). Last, the method of questionnaire administration can also influence responses and thus the

results of a survey, making comparisons of data produced by different types of administration difficult to compare (Bowling, 2001).

Attention should be paid in distinguishing measurements between individual and group assessments. In group comparisons usually the emphasis lies in testing hypotheses, but in measuring individuals the emphasis is about estimating values. Thus, a higher degree of precision, reliability, and validity of the measurement is necessary (Donaldson, 2008). This is the reason why writers propose different acceptable levels of psychometric properties for groups and individuals (Nunnally and Bernstein, 1994; Streiner and Norman, 2008).

4.3.4 Types of Measures

There are many attempts to classify HRQoL measures and various criteria have been used. Thus, measures are classified according to:

- The types of scores they produce;
- The range of populations and concepts covered;
- The weighting system used in scoring items (Patrick and Erickson, 1993).

The first type of classification produces measures such as: *single indicators* which produce a single score obtained from a single item, *single indices* that produce a single score but summarise multiple concepts, *profiles* producing multiple scores on the same or related domains, and *batteries* that produce multiple scores of independent domains (Fayers and Machin, 2007).

The second type of classification covers generic and specific measures which are divided into disease, domain and population specific measures. *Generic* measures are used across various types and severity of diseases, different treatments or interventions, and different demographic or cultural subgroups. *Disease-specific* measures are used to assess or detect minimally important changes of specific diseases. *Domain-specific* measures are developed to assess a condition or symptom.

Population-specific measures are designed to address population sub-groups usually characterised by age, ethnicity, or medical condition (*ibid*).

When the weighting system is used as a classification criterion two types of measure emerge: The *utility* weighting measures, with weighted preferences from patients, providers, or community. Measures are also classified according to the type of *statistical* weighting with items weighted equally or from frequency of responses.

Other taxonomies propose that measures can broadly be classified under seven categories: generic, disease specific, dimension-specific, site or region-specific, summary items, individualised, and utility measures (Fitzpatrick *et al.*, 1998; Garrat *et. al.* 2002a). The vast majority of them fall within the first two categories namely the generic and disease-specific ones.

Two final points should be made. First, having described the classification criteria, it should be noted that because the criteria used are more than one and are different in essence, groups are not mutually exclusive and instruments do not necessarily belong to one group only. Another interesting point concerning the nature of quality of life measures has been raised by Bowling, who notes that although QoL is usually defined in positive terms it is mostly measured and presented in negative terms. Thus, most types of measures are expressed in terms of what has been lost rather than what exists in someone's life (Brown *et al.* 2004).

4.3.4.1 Generic measures

Generic measures are designed to summarize a wide spectrum of health status or quality of life (Patrick and Erickson, 1993). They can be used across different types and severities of disease, medical treatments, health interventions, and different demographic and cultural subgroups. Additionally, generic measures are useful for assessing the burden of populations suffering from chronic medical or mental conditions compared with healthy populations. Also, they have been proved useful in comparing health outcomes across different health care delivering systems. Thus,

by allowing the comparisons of different populations help decision making, resource allocation, and make policy implementation possible (Patrick and Deyo, 1989; McHorney *et al.* 1994, Anderson *et. al.* 1997).

They include three types of measures: single indicators, health profiles, and indices (McDowell, 2006). Single indicators express an aggregate of separate scores with a single number. Health profiles present separately the various aspects of health, while health indices combine these aspects into an overall score (*ibid*).

In literature generic measures are often defined as QoL measures but they should be called health status measures, because their main focus is on physical symptoms (Fayers and Machin, 2007). The underlying assumption of this approach is that low levels of health status indicate poor quality of life. However, this is not always the case, since there are cases where efforts to achieve high levels of health status may damage quality of life. The management of diabetes is one of these cases where a health status measure used for assessing the level of quality of life can lead to misleading conclusions (Bradley, 2001).

Generic measures could in some cases elicit information relevant to quality of life of a specific condition or disease, but in order to accomplish this they would have to be of enormous length (Bowling, 2001). In such a case many of the items contained have little or no relevance to a specific group of patients. If the length is reduced the number of items covering a certain domain has to be reduced, resulting in reduced ability to capture changes in individual patients or differences among them (Streiner and Norman, 2008).

Since they address a wide range of issues generic measures may lack items relevant to the disease, thus failing to focus on certain aspects of the disease or treatment that might be of particular concern to patients (Snoek, 2000). As a result these instruments may lack sensitivity, specificity and utility within a disease entity (Anderson *et. al.*, 1997). An example of this is the SF-36 and diabetes. The measurement of quality of life of people with diabetes and the impact that the disease

has on it is a very complicated issue. This is because various factors enter into diabetes life and its management. People with diabetes need a high degree medical care, life-time medication, health literacy and extensive self-management. Furthermore, diabetes is a condition that creates a wide range of complications. The problem in assessing diabetes-related QoL with generic-health status measures is that individuals do not react the same to medication, self-management, impairment, or perceive disease in various ways, and therefore their QoL is affected differently. Generic measures cover domains like pain, mobility and physical function, areas of little importance to people with diabetes, but ignore restrictions on diet, which is something very important for patients and which is considered to have the most negative impact of diabetes on QoL (Bradley –Speight, 2002). Moreover, generic measures are not sensitive to detect small, clinically important changes of specific conditions (Guyatt *et al.* 1986). To detect these changes generic measures should be implemented by disease-specific measures.

4.3.4.2 Disease-specific measures

Disease-specific health-related QOL instruments are designed for application to individuals, conditions or diseases, domains, or populations (Patrick and Deyo, 1989). The rationale for these instruments is that they are measures narrowly focused giving more detailed information about the disease or condition of interest (Bowling, 2001). There are particular issues in all conditions or diseases which contribute to a much greater extent to QoL than other issues (Orley *et. al.* 1998). Pain for example is a major concern for people with orthopaedic problems, but not for insulin dependent people with diabetes to whom the fear of hypoglycaemia is the dominant concern (Bradley, 1994). Also, a diabetes-specific QoL measure should be focused on dietary restrictions, which for people with diabetes is a major issue compared with patients with other diseases (Bowling, 1996).

Disease- specific measures are often developed aiming at detecting minimally important changes in certain conditions or diseases in clinical trials or longitudinal

studies (Guyatt *et al.* 1986). This is because disease specific measures are more sensitive (responsive) to changes that occur over time (Patrick and Deyo, 1989).

However, the advantage of disease-specific measures that focus on the impact of a disease or an intervention might also be considered as a disadvantage. Every intervention has “primary” as well as “secondary” endpoints or side-effects. From the clinical - provider point of view, measurement is mostly focused on the main effects of the intervention, while the patient is concerned with health as a whole and not a particular aspect of it. For the patient there is no distinction between main and side effects, there are only general endpoints and effects, which should be measured for establishing preferences and deciding policies (Dowie, 2002).

Moreover, disease-specific instruments cannot provide information for comparisons between diseases, as they are focused on particular diseases. Therefore, disease specific measures are not very suitable for examining the effectiveness of alternative or competing policies and health care programs. As a result, the final choice about the type of measure to be chosen depends entirely on the structure of the decision different types of measures should be used for different decisions (Dowie, 2002).

4.3.4.3 Global questions v multi-item measures

- *“When I use a word” Humpty Dumpty said in a rather scornful tone, “it means just what I choose to mean – neither more nor less.*
 - *“The question is”, said Alice, “whether you can make words mean so many different things”*
 - *“The question is” said Humpty Dumpty, “which is to be master – that’s all”*
- Lewis Carroll: Through the looking-glass*

Another issue concerning the types of measures is the value of the global questions. That is whether the answer to only one question can give a realistic picture of the existing situation. The controversy over the value of global questions for the assessment of QoL starts with the onset of the concept in literature in the 1970s (Schneider, 1976).

There are writers who believe that:

“The simplest and most overtly sensible approach to measure quality of life is to use global rating scales. These ratings... can allow expression for the disparate values and preferences of individual patients” (Gill, 1995).

Global items are necessary because:

“Quality of life may encompass not only health-related factors, but also many non-medical phenomena, such as work, religion and relationships.”

Gill extended his argument, and together with Feinstein, argued that:

“To ensure that separate effects of health-related factors and nonmedical phenomena are suitably determined and distinguished, investigators should ask patients to give two global ratings, one for overall quality of life and another one for health-related quality of life” (Gill and Feinstein, 1994).

However, there is a considerable disagreement among investigators about the value and use of global questions in quality of life assessment. According to Fayers and Manchin (2007):

“Global questions are often regarded as too vague and non-specific to be used on their own”.

Moreover, the problem of QoL definition and perception in assessing quality of life enters the global and single-item discussion. The meaning of QoL is not just an academic controversy that torments the scientific community only but a practical problem when the term is used in questionnaires concerning patients’ perception of QoL. As Hyland (1998) argued:

“If a global scale of quality of life is used, i.e. when patients are asked directly to evaluate their quality of life on a single scale, the meaning of the term quality of life will be interpreted differently by different respondents”.

Joyce (1994) takes the argument even further arguing that single item questions have untestable reliability.

Reports of various investigators cannot provide concrete answers on the issue. There are studies that support the possibility of substitution of a multi-item scale with a global single-item question (Jenkinson *et. al.* 1995; Hurny *et. al.* 1996) and others that argue that this substitution, although desirable, is not feasible (Barofsky *et. al.* 2004).

In conclusion, QoL is a construct and as such cannot be measured directly. Psychometric theory suggests that in these cases a series of questions tapping various aspects of the same concept have to be asked. Although global questions can be simple, reliable, and valid they cannot be detailed enough to provide information on various dimensions of QoL.

Multi-item questionnaires on the other hand provide more information on QoL dimensions, are more stable, precise, and reliable, more consistent in terms of results, and they are less prone to distortion from various biases, avoiding random errors (Bowling, 2005d). Thus, there is a trade-off between simplicity and precision and these are the criteria for choosing between them. The needs and the purpose of the study should guide the investigators for their final choice (*ibid*). However, this final choice should not necessarily be of a disjunctive nature. This is because:

“Single item measures can be used alongside multi-dimensional measures, and are useful as broad summary ratings of diverse aspects of respondents’ health, QoL, and HRQoL...” (Bowling, 2005d).

Nevertheless, most diabetes-specific questionnaires seem to underestimate the value of global questions.

Chapter 5: Diabetes and Quality of Life

5.1 Introduction

There has been a growing interest in the last few years in determining the factors that affect quality of life of people with diabetes. Rubin and Peyrot (1999) argue that:

“The literature concerning associations between quality of life and disease specific, demographic and psychosocial variables in people with diabetes is larger than that for differences in quality of life between people with diabetes and the general population, or between diabetes and other chronic conditions”.

When assessing the impact of diabetes on quality of life, the factors that could be considered predictors are a controversial issue. Investigators report different, and in many cases conflicting, findings for various predictors of QoL and their role in determining QoL. This could be attributed mainly to three factors. First, it is the complexity of the concept and the definitional problems, discussed in the previous chapter, that create some confusion regarding the nature of QoL. The second factor refers to the different instruments used for the assessments. These instruments tap different dimensions of QoL as well as present their results in various ways, making comparisons unreliable (Wandell, 2005). A third factor that influences health outcomes and thus quality of life of chronically ill is the health care system. Different systems produce different health outcomes, thus making conclusions about certain predictors unreliable (Ware *et al.* 1996).

5.2 Variables associated with QoL in diabetes

Diabetes has a serious impact on quality of life. Diabetes, as a chronic disease affects almost all aspects and domains of life. However, diabetes as a disease is not experienced in the same way across different population around the world, different ages, sexes, or among people with different socioeconomic status or education level.

Rubin and Peyrot (1999) in a very influential narrative review described three types of determinants associated with quality of life in people with diabetes: Medical predictors, attitudinal predictors and demographic predictors. Medical predictors include the type and duration of diabetes, the treatment regimen, glycaemic control, and presence of complications. Attitudinal predictors include self-efficacy, locus of control, and social support. Demographic predictors of diabetes are gender, socioeconomic status, education level, ethnicity, age and marital status.

The word ‘predictor’ is used by Rubin and Peyrot (1999) to describe all the variables that are hypothesised to affect quality of life. The word not only describes an association between two variables but it also implies the direction of causality between the variable and the QoL. The fact that the causality among all those variables is complex and sometimes reciprocal does not permit the use of the word ‘predictor’ in its absolute sense, as nothing can be considered *a priori* as predictor or outcome.

The role of access to health-care, either in the form of geographical proximity or in relation to socioeconomic status, a subject that has not received particular attention by researchers, is a central question for this study. Thus, the role of the health-care system as a variable of diabetes-specific quality of life is going to be examined together with the other determinants. Attitudinal variables like self-efficacy or social support are also of great importance for diabetes, and probably the subject of a future investigation, but they are beyond the scope of this study.

5.2.1 Type of Diabetes

Bradley and Speight (2002) using the 13 item ADDQoL pointed out that patients with either type of diabetes almost always experience a negative impact in QoL. However, there are differences among patients with different type of diabetes with type 2 diabetes patients reporting better QoL than those with type 1 (Jacobson *et al.* 1994; Glasgow *et al.* 1997; Polonsky *et al.* 1995). These differences are mitigated for

type 2 diabetes patients on insulin regimen, who reported greater impact of diabetes on quality of life than the ones on oral medication-dietary regimens. Thus, these differences might be attributed to different treatment regimens and not to the type of diabetes *per se*.

5.2.2 Diabetes Control

There is a widely accepted view that diabetes control is associated with quality of life in various ways. This is because control is the end-result of different aspects and activities. Food intake, oral medication or insulin dose, psychological factors, exercise and physical activity are some of the factors influencing diabetes control. Thus, the continuous attempt of finding a balance among these factors usually affects quality of life in many different ways (Eiser and Tooke, 1993; Chyun *et al.* 2006).

Glucose and blood pressure control result to reduction of complications, and thus to better QoL. The findings of the initial UKPDS as well as 10 years follow-up studies confirm the association of diabetes-control and complications (UKPDS, 1998a; UKPDS, 1999; Holman *et al* 2008a; Holman *et al.* 2008b). Patients with good control report better QoL than those with poor control (Shen *et al.* 1999). Rubin and Peyrot (1999) stated that long term glycaemic control, as long as it is not associated with burden or hypoglycaemia, results to better quality of life. Moreover, they note that this is more obvious when diabetes-specific measures which capture patient perceptions of symptoms are used for QoL assessment.

5.2.3 Treatment regimen

Insulin-dependent patients report a greater impact of diabetes on their lives. Using the ADDQoL Bradley *et al.* (1999) found that in 12 out of 13 items of the measure the impact of diabetes was greater for insulin-dependent patients. Similar results, with patients on insulin reporting the lowest quality of life, have been reported by

various other writers (Meadows *et al.* 2000; Jacobson *et al.* 1994; Glasgow *et al.* 1997). Rubin and Peyrot (1999) argued that research findings support the view that treatment intensification from diet only, to oral medication to insulin is associated with decrements in QoL.

Differences have also been reported among insulin treated diabetes patients, depending on the type of insulin they receive. Kotsanos *et al.* (1997), using the Diabetes Quality of Life Clinical Trial Questionnaire, found that patients receiving the first acting insulin analogue (insulin lispro) appear to have higher quality of life, treatment satisfaction, and treatment flexibility than those using regular human insulin. Similar results have been reported by Howorka *et al.* (2000) as well as by Bott *et al.* (2003) who used insulin aspart as analogue.

The type of insulin intake might also be a QoL variable. Pump users are reported to score significantly higher than patients injecting insulin, in domains such as ‘worries about the future’, ‘leisure time flexibility’, and ‘diet restrictions’. Also, patients with a flexible adaptation of insulin dosage (i.e. insulin intake according to food consumption), achieved better scores in ‘social relations’, ‘leisure time flexibility’, ‘worries’, and ‘diet restrictions’ (Bott *et al.* 1998).

However, not all researchers agree with the above views. Polonsky *et al.* (1995), contrary to their initial hypothesis, found no significant difference between insulin and oral medication treated type 2 diabetes patients. Similar findings were also reported by the UKPDS Group in 1999 (*op.cit.*) who argued that intensive policies of insulin therapy had no greater impact on QoL than other treatments of diabetes (UKPDS Group, 1999).

5.2.4 Complications

It has been established by various investigators that diabetes complications is the most important determinant of QoL (Rubin and Peyrot, 1999; Jacobson *et al.* 1994; Trief *et al.* 1998; Anderson *et al.* 1997; Glasgow *et al.* 1997; Polonsky *et al.* 1995). Diabetes complications are divided into two main categories: microvascular and macrovascular. Retinopathy, nephropathy, and neuropathy are considered to be the most common microvascular complications. Macrovascular ones include coronary heart disease, cerebrovascular disease and stroke. Diabetes-patients with macro vascular and micro vascular diseases, especially nephropathy, report lower quality of life compared with patients without any of these complications (Lloyd *et al.* 1992). In 1999, the UK Prospective Diabetes Study Group (UKPDS, 1999) announced that the results of two cross-sectional studies show that patients with macrovascular complications reported significantly worse health, problems with mobility, and reduced vigour. Patients with microvascular complications reported more tension and total mood disturbance. Wandell (2005) argued that macro vascular diseases, especially coronary heart disease, and non-vascular diseases, are the strongest predictors of QoL in diabetes. He also found that microvascular diseases had only weak associations with QoL. Foot ulcers have a major negative effect on all aspects of quality of life, particularly on the physical domain because of reduced mobility (Brod, 1998; Goodridge *et al.* 2005; Ribu *et al.* 2008).

5.2.5 Duration

Research findings show that the relationship between diabetes duration and quality of life is inconsistent. Some investigators argue that duration of either type of diabetes has no influence on quality of life (Jacobson *et al.* 1994; Parkerson *et al.* 1993). However, other writers argue that development of diabetes early in life may have a negative effect on personal development in the domains of autonomy, independence, self-perception, and social integration (Gafvels *et al.* 1993; Aalto *et*

al. 1997). At the same time an early onset of the disease facilitates long term psychological adjustment and management of diabetes. On the other hand, according to Bott *et al.* (1998), short duration is positively related to physical components of QoL with young patients reporting fewer physical complaints and greater leisure time flexibility. Similar findings were also reported by Lloyd and Orchard (1999).

It is interesting to note that duration should not be seen only as a variable in its own capacity as it might also affect the importance of other variables. Jonsson *et al.* (2001) argued that for young patients the main variables of self-rated health in the onset of the disease were social class, marital status, and employment. Eight years after the diagnosis the importance of variables changed with gender being the most powerful one, followed by age and socioeconomic factors.

Last, duration is indirectly related to QoL through the complications attributed to diabetes. These complications occur at an increasing rate during the course of the disease, thus influencing QoL (Klein *et al.* 1998).

5.2.6 Socio-economic Status

Socio-economic status (SES) is consistently related to health outcomes, although the mechanisms concerning this relationship are not adequately explained. People with diabetes are unlikely to be immune from this general pattern of SES and illness. Various studies prove a powerful association between SES, morbidity and mortality (Robinson *et al.* 1998; Chatuverdi *et al.* 1998; Roper *et al.* 2001). SES is also connected with high rate of complications and low use of medical care (Bachman *et al.* 2003). SES can influence diabetes in many different ways. It can influence the access to care as well as the quality of care (Muhlhauser *et al.* 1998; McCall *et al.* 2004; Hippisley-Cox *et al.* 2004). It can also influence diabetes-related knowledge, social support, communication with providers, ability to receive recommended medication and treatment, and dietary and treatment regimens (Brown *et al.* 2004).

Low SES is an identifiable risk factor for poor quality of life. However, although the association of health and SES pertains mainly to low levels of SES, it is not a characteristic of poverty and deprivation. There is evidence of a graded association with health at all levels of SES and not only at the lower levels of it (Adler *et al.* 1994). Glasgow *et al.* (1997) reported significant and large differences in the quality of life between diabetes patients of different income levels. Similar findings have been reported by various other writers (Bott *et al.* 1998; Camacho *et al.* 2002; Lindsay *et al.* 2011).

5.2.7 Gender

Gender in diabetes-related QoL has not received sufficient attention by researchers. Many articles do not include in their findings gender composition and more than half of those that include it fail to examine the differences between sexes (Rubin and Peyrot, 1998). Nevertheless, the majority of the studies that examined the gender issue found that they were statistically significant differences on quality of life between men and women.

Men report higher quality of life in general compared with women (Eiser *et al.* 1992; Glasgow *et al.* 1997; Lloyd and Orchard, 1999; Unden *et al.* 2008). However, most writers differentiate between men and women according to certain domains of quality of life. Jacobson *et al.* (1994) found significant differences between sexes on two domains only, with men reporting less impact of diabetes and fewer diabetes-related worries. Rubin and Peyrot (1998) argued that men enjoy higher quality of life than women, especially regarding dietary issues and overall treatment satisfaction. They also achieve better glycaemic control, fewer complications, and they are more confident in managing their diabetes. Women on the other hand show higher rates of anxiety and depression, which in turn have a negative impact on glycaemic control and complications (Gafvels *et al.* 1993). Hammond and Aoki (1992) reported that women complained about more symptoms, less diabetes-related morale and lower well-being. Boyer and Earp (1997) using the D-39 measure found

that women scored higher than men on the energy-mobility, control and anxiety-worry scales, while men proved to have more troubles on sexual functioning than women. Shen *et al.*(1999) using the Diabetes QoL Clinical Trial Questionnaire (DQLCTQ: Chapter 6 and Appendix A) reported that male patients perceived better quality of life than females in 30 out of 34 domains.

There are doubts on whether the differences between men and women on self assessed QoL are real or artificial because men in general are willing to pronounce themselves successful and less willing to admit problems. On the other hand, it is more acceptable for women in western societies to be more sensitive to physiological changes and express their emotions overtly (Nathanson 1975; Bradley, 1980; Marcus and Seeman, 1981). However, observed differences in the number of complications and glycaemic control suggest that some differences rather exist on the real level.

5.2.8 Age

The association between age and QoL of people with diabetes is not very clear. It is certain though that QoL of elderly individuals differs from that of younger adults. It is natural older people to report problems especially regarding general health but when certain domains are assessed results are more complicated. Trief *et al.* (2003) compared HRQoL of insulin-treated diabetes patients aged 65 years or older with that of young patients aged between 30 and 64 years. The comparison was performed with the SF-36 and three diabetes-specific measures. The SF-36 results showed that patients from the older group reported more physical problems but scored better in social functioning. Lindsay *et al.* (2011) using the PAID questionnaire (Problem Areas in Diabetes: Chapter 6 and Appendix A) reported a significant deterioration of QoL scores as age increased.

However, other diabetes-specific measures showed that elderly patients are coping better and reported less distress and greater satisfaction with aspects related to diabetes. Similar findings were reported by Brown *et al.* (2004). The findings of

Glasgow *et al.* (1997) found that young patients reported better QoL in physical as well as social functioning.

Jacobson *et al.* (1994) found age to have only a limited influence on overall diabetes-specific quality of life, while Hammond and Aoki (1992) reported that age was positively correlated with diabetes-related morale and well-being subscales of the Diabetes Impact Measurement Scale (DIMS: Chapter 6 and Appendix A). On the other hand according to Bott *et al.* (1998) young patients report better quality of life in the domains of physical complaints and leisure time flexibility.

Trying to assess the relation of age with diabetes-specific quality of life, the level and quality of 'realised' health care should be considered as a confounding variable. Weiner *et al.* (1995), assessing the quality of care at primary care settings, found that elderly people do not appear to receive optimal care, with those living in rural areas receiving even less care than those living in urban locations (*ibid*). Therefore, reduced care combined with the natural debilitation that ageing causes might be major influences in certain domains of quality of life.

5.2.9 Education

Educational status is an important factor for health as well as QoL. In a nationwide study in Sweden it was shown that low-educated people with diabetes had a 40% excess in all-cause mortality compared with high-educated patients (Nilsson *et al.* 1998). According to Glasgow *et al.* (1997) people with diabetes who had college education had higher QoL compared with people with high school education or less.

Education is also related to diabetes complications. According to Peyrot and Rubin (1997) college graduates with diabetes experience less than half the risk of psychological disturbance or depression compared with those who did not graduate from high school.

However, Jacobson *et al.* (1994) using a diabetes-specific and a generic measure, the Diabetes Quality of Life (DQOL: Chapter 6 and Appendix A) and the SF-36 respectively argued that education level did not influence quality of life.

5.2.10 Marital Status

Research indicates that there is a strong relationship between marital status and quality of life. Jacobson *et al.* (1994) reported that divorced or separated diabetes patients experience worse quality of life than those who were single or married. Married patients run a lower risk for diabetes-related depression (Peyrot and Rubin 1997) and they report higher treatment satisfaction (Bott *et al.* 1998). Boyer and Earp (1997) argued that single people feel a greater impact on energy-mobility and anxiety-worry scales, but less impact on sexual functioning than married ones.

Marital status is not the only factor that affects quality of life in diabetes. Trief *et al.* (2001; 2002) argued that even quality of marriage is associated with quality of life. Better marital satisfaction is related to less impact of diabetes, less diabetes-related distress, and better diabetes-specific as well as general quality of life.

5.2.11 Quality of care

There are writers who believe that improving health is not an end in itself but a means or part of the attempt to improve quality of life. Ware (1987) argued that:

“The goal of the health care system is to maximise the health component of quality of life, namely health status”.

However, the types of health care organisation, the level of care, equity and the type of access to care are controversial issues that do not have unequivocal answers. Moreover, the evaluation of health care as a whole is almost an impossible task. Klein *et al.* (1961) argued that:

“...it seems quite likely that there will never be a single comprehensive criterion by which to measure quality of patient care” (cited by Donabedian, 2005).

Some writers believe that health care is a predictor of HRQoL. Ashing-Giwa (2005) argues that:

“Traditional HRQoL framework follows a predominantly individual centred paradigm excluding contextual domains (e.g. health care system, cultural and socio-ecological factors)”.

According to his model of HRQoL systemic factors, such as access to care, quality of care, and the quality of physician-patient relationship, affect overall HRQoL. Leufstedt (2002), the president of the Swedish Diabetes Association, epitomised the relationship between the diabetes patient and health care arguing that the patient is not part of health care team but rather health care is part of the care of the person with diabetes.

Although the actual level of quality of care cannot be easily assessed, empirical evidence shows that there is an association between quality of life and quality of care. Collins *et al.* (2009) using multivariate analysis, the ADDQoL as quality of life measure, and allowing for age, sex, complications and other confounders, found that there are differences in QoL among people receiving care at different levels. Patients receiving structured GP care are almost twice as likely to have higher quality of life, relatively to others receiving traditional hospital care or hospital/GP shared care.

Chapter 6: Aims and Objectives

6.1 Aims of the study

Internationally, QoL and diabetes appears not have received the attention commensurate with the size of the problem. However, in Greece, the field is virtually untouched and there is not a diabetes-specific measure for assessing the QoL of Greek patients.

The principal aim of this study was:

- To examine the QoL of people with diabetes in Greece and to investigate to what extent self-assessed QoL is associated with demographic, socioeconomic, and medical factors.

Subsidiary aims included:

- The rating of the impact of diabetes on various domains of life using the Audit of Diabetes Dependent Quality of Life measure, translated and culturally adopted for this study;
- The assessment of health status of people with diabetes in Greece using the SF-36v2 Health Survey.

6.2 Objectives

The following research objectives were identified:

- to examine the relationship between various medical factors and the QoL of people with diabetes in Greece;
- to investigate whether there is any association between the area of residence and QoL of people with diabetes in Greece;
- to explore the relationship between socioeconomic status and QoL of people with diabetes in Greece;

- to examine the relationship of demographic, socioeconomic, and medical factors and health status;
- to investigate any associations between health status components and QoL domains;
- to examine the structure of the existing diabetes-care system in Greece as well as its relation, if any, to diabetes-related QoL;
- to use the knowledge that will be gained by making recommendations about the restructuring of the diabetes-care system in Greece.

To achieve these aims and objectives, the following steps were required:

- Selection of the most suitable HRQOL (diabetes-specific) measure through a systematic search of the literature (Chapter 8);
- Translation and cultural adaptation of the selected HRQOL measure into Greek (Chapter 9);
- The construction of a questionnaire for collecting the socioeconomic and medical variables of the respondents (Chapter 10);
- A cross sectional survey using the diabetes-specific QoL measure and SF-36 (Chapter 10);
- Testing of the translated measure for reliability and validity in Greece (Chapter 11);
- Rating of diabetes impact on various domains of life using the diabetes-specific QoL measure (Chapter 12);
- Comparison of the HRQOL with generic SF-36 (Chapter 14).

In Part II: Selection of a diabetes-specific QoL instrument for the Greek population (Chapters 7 and 8) of this thesis, the properties of QoL instruments to be considered during the development of an instrument are discussed. An understanding of these properties was considered necessary for the review and the selection of the most suitable HRQOL (diabetes-specific) measure for the Greek population. 11 diabetes-

specific QoL instruments were identified from a search strategy involving five databases and the retrieval of an initial 2020 articles.

In Part III: Producing the ADDQoL-Gr (Chapter 9), translation into Greek and cultural adaptation to the Greek population of the selected HRQOL diabetes-specific measure was performed. This follows the defined process as described by the Agreement for the translation and use of the ADDQoL 19 rev 1.3.06 signed by the owner of the instrument Prof. Clare Bradley, Mrs J. Ross of the Royal Holloway-University of London, Prof. Ann Bowling of the UCL and me.

In Part IV: Survey of the Greek Population (Chapters 10 and 11), the cross sectional survey of the Greek population using the HRQOL, SF-36 (for which a translated version for the Greek population exists), a demographic-socioeconomic-medical questionnaire including construction and tests on the validity of the ADDQoL-Gr are described. The latter involved testing the translated instrument for its psychometric properties. This is necessary because “*the psychometric properties cannot be assumed to travel well*” (Bradley, 1996). The results are compared with the results of the original instrument as well as the results of its translations into other languages (Bradley *et al.* 1999; Kamarul *et al.* 2007; Da-Costa *et al.* 2006).

In Part V: Diabetes and Quality of Life in Greece (Chapters 12 and 13) the findings of the main QoL study are reported, results are discussed and the impact of diabetes on QoL is examined. It is in this part that analysis and synthesis takes place in the sense that the findings are compared and contrasted against each other, among the various sub-groups of the respondents, as well as against the findings of the international literature. Chapter 12 deals with the impact of diabetes on the lives of Greek patients, using the ADDQoL-Gr. This impact is assessed both as a whole (total weighted and unweighted) and according to the 19 different domains of the instrument. Various statistical techniques are used and the results of this work are discussed and compared with the international literature. Chapter 13 assesses the QoL sub-groups clustered according to demographic, socioeconomic or diabetes-related characteristics of the respondents. In this sense predictors of diabetes-related quality of life are identified and their contribution to QoL is assessed.

In Part VI: Diabetes and Health Status the impact of diabetes on health status is investigated and the association of medical and socioeconomic variables with health components of the SF-36.

PART II: Selection of a diabetes- specific QoL instrument

Chapter 7: Properties of Quality of Life Instruments

7.1 Introduction

The merits as well as the shortcomings of disease-specific quality of life measures in general have already been discussed. However, before the selection and application of an instrument is decided certain problems have to be met.

The selection of an instrument is complicated, and potentially as a consequence of this has lacked a systematic approach. According to Polonsky (2000) many writers choose one of the following rules when selecting a QoL instrument: a) Use whatever others seem to use more often; b) assume that HRQoL correlates with psychological status and use any instrument that tackles some aspect of the patient's psychology (e.g. depression) and; c) use any questionnaire that includes "quality of life" and "diabetes" in its title.

In order to explain the selection of the appropriate instrument for this research, to avoid any theoretical misconceptions as well as the scientific loopholes described by Polonsky (*ibid*), it is necessary to understand and clarify the concepts involved in the process. Moreover, the new instrument that has to be produced for the measurement of the Greek population with diabetes has to undergo procedures that will prove it as a valid a reliable instrument.

This chapter is an introduction to the theory related to instruments' development, an attempt to define some concepts that suffer from some degree of ambiguity, and provide elements of the background which is necessary for the achievement of the two goals described in the previous paragraph.

The first problem in the attempt to develop or evaluate the instruments is the lack of a unanimously accepted definition of Health Related Quality of Life (HRQoL). Such a definition would provide the basis against to which the conceptual underpinnings of the instruments would be compared and its psychometric properties would be

assessed. Thus, the inclusion criteria, the review as well as the final choice of a measure was a value judgement, dependent to a great extent on the accepted definition of HRQoL.

Another difficulty with QoL instruments lies in the field of property measurement. The attributes of the instruments concerned HRQoL are not physical attributes, but psychological ones. Psychological attributes cannot be directly observable, physically measured, or operationally defined. (Cronbach and Meehl, 1955). These attributes are “hypothetical constructs”.

“A construct can be thought of as a ‘mini theory’ to explain the relationships among various behaviours or attitudes” (Streiner and Norman, 2008).

As such, they cannot be measured directly, but by using various indicators that can explain a great part of the construct and never the full spectrum of it. In this sense no construct measurement can be fully complete. These not directly observable constructs lack evidence independent of their measures. As a result no “gold standard” can be created for such measurements. However, despite the fact that they are “hypothetical” these constructs have an ontological status on their own; that is, they exist independently of their measurements (Hyland, 1993).

The lack of a “gold standard” that might be used for the instruments’ evaluation creates in turn various difficulties concerning:

- The attributes that should be used as criteria for the evaluation;
- Methodology for the assessment of a particular property;
- Terminology. In some cases it is impossible to clarify the exact meaning, content and definition of these criteria. Quite often terms like “discriminant” and “discriminative” validity, “sensitivity to change” and “responsiveness” or even “acceptability”, “burden”, and “feasibility” are used interchangeably;
- Index interpretation. That is a compilation of rules aiming to explain the results of a test. This is another confusing topic. As Guyatt *et al.* (1998) pointed out:

“Several questionnaires on quality of life related to health are available, but interpreting their results may be difficult”.

7.2 Conceptual - Measurement Model

The conceptual model is the starting point for the development of an instrument. It is:

“A rational for and description of the concepts and the populations that a measure is intended to assess and the relationship between those concepts” (SACMOT, 2002).

The conceptual model contains theory about the concept to be measured, literature review, any new research carried out for or during the development of the new measure and/or any existing scales that have been used and on which the development of the instrument was based. It also contains information about the conceptual and empirical bases for its item generation.

7.2.1 Item generation

It is probably the most important part of an instruments' development. As Streiner and Norman stated:

This is far from being a trivial task, since no amount of statistical manipulation after the fact can compensate for poorly chosen questions; those that are badly worded, ambiguous, irrelevant, or-even worse- not present (Streiner and Norman, 2008).

There are a number of factors influencing the selection of items in an instruments' construction. First, it is theory that should play an important role in this process. This term encompasses formal and refutable models of how things relate to one another, as well as vaguely formed hunches of how people behave (*ibid*). Research helps the developers of a questionnaire to create items that have been shown empirically to be the characteristics of the target group (*ibid*). Also, it is the developer's personal judgement that has a significant role in items selection and the structure of the instrument. Sometimes this personal judgement can be the sole basis for the construction of the whole instrument. This is something that even the developers cannot deny. Ware himself, the main developer of the SF-36, in the preface of the manual, accepted that it was he who decided on the eight dimensions of the SF-36 out of dozens under study in the MOS (Ware *et al.*, 1993).

The patient, expert and clinician's involvement in conjunction with the place and the period that the instrument was developed gives an idea about the *culture* of the instrument, as "HRQL instruments are not *"culture free"* but *"culture full"* (Fox-Rushby and Parker, 1995). This is an important argument for the necessity of patient participation in instruments' development; without it the culture of the researchers is reflected in the items as they are:

"the most influential group of people in the development of generic instruments to date" (*ibid*).

Another characteristic of instruments analysed in this section is the "measurement model". A measurement model according to the SACMOT (2002):

"Operationalizes the conceptual model and is reflected in an instrument's scale and subscale structure and the procedures followed to create scale and subscale scores".

Item scaling is an important feature of an instrument. This is the range of options available for patients in answering each question (Kirshner and Guyatt, 1985). This characteristic is not simply a way of facilitating or improving the acceptability of a measure by the respondents. It is important when correlations with a criterion measure are examined, it facilitates the uniform interpretation of results and its grading determines to a great extent the ability of the instrument to register changes (*ibid*).

The items generated have to undergo tests such as Factor Analysis or Principal Component Analysis in order to obtain information about dimensionality and distinctiveness of multiple scales.

7.2.2 Factor Analysis

Factor analysis (FA) consists of a number of statistical techniques aiming to simplify complex sets of data. The aim of this simplification is to explore the structure of these data and therefore their meaning (Howitt and Cramer, 2005). FA takes a large set of variables and tries to reduce them by finding those which correlate most with each other, producing a smaller set of variables called factors. It is based on the idea

that an array of variables can be described in terms of a reduced number of underlying factors (Streiner-Norman, 2008). “Factor” is a dimension or “underlying construct” or simply “construct”, which is a condensed statement of the relationships (correlations) between a set of variables. A factor is a construct operationally defined by its “factor loadings”. Factor loadings are the correlations (r) of a variable with a factor (Kline, 1994).

FA is used to define the dimensionality of an instrument. The dimensionality of an instrument is important because it is an essential component of construct validity (Slocum-Gori and Zumbo, 2011). In this respect it is used to assess construct validity. In order to understand the use of FA a distinction should be made between Exploratory and Confirmatory Factor Analysis.

7.2.2.1 Exploratory Factor Analysis

According to Streiner and Norman (2008) Exploratory Factor Analysis:

“Is a hypothesis generating technique, used when we do not know beforehand what relationships exist among the variables”.

Exploratory FA aims to explore a set of data, by identifying the main constructs or dimensions. It shows how the variables cluster together to represent underlying constructs, even if these have not been formally defined. It also shows the importance that the variables have in the field. In the Exploratory Factor Analysis there are no *a priori* hypotheses based on theory or previous research about the composition of the subscales and this form of analysis is used to discover the latent variables of the scale (Floyd and Widaman, 1995).

7.2.2.2 Confirmatory Factor Analysis

As mentioned above Factor Analysis in its exploratory role is a hypothesis generating technique. However, FA is also used to confirm and evaluate the hypothesised scales of the conceptual model. In this respect Confirmatory Factor Analysis is used as a hypothesis testing approach (Streiner-Norman, 2008: 413). The factor structure

which appears in the exploratory factor analysis, has to be proved real and capable of supporting the proposed conceptual structure. To this end, initially the factors loadings of the variables have to be hypothesised. CFA is then used to fit these loadings in the target matrix (high, low or zero loading) as closely as possible (Kline, 1994).

7.2.2.3 Factor Rotation

Factor rotation is a technique for improving interpretation of the results by presenting the pattern of loadings. Factor loadings are the correlations of the variables with a factor. This is necessary in order to facilitate the discrimination between factors. Items should have a high loading on one factor only and a zero or insignificant loading on any other factors. If a factor loads on any other factor (cross loading), it means that the item may refer to something other than intended by the developer and in most cases it is removed.

By rotating the factors a maximum loading on one factor is obtained, minimising the loadings on other factors, and the pattern of the factor loading is facilitated. There are two types of rotation: Orthogonal and Oblique.

Orthogonal rotation is used when there is a sound theoretical assumption that the factors are independent (not correlated) and wanted to be kept so. By rotating the factors orthogonally their overlapping is minimised, enhancing the interpretability of the instrument (Bowling, 2005a).

Oblique rotation is used when the underlying factors are supposed to be related and can be allowed to correlate with the rotation. The results of the oblique rotation, due to factor correlation, are not very easy to interpret and should be used only in cases where there is a sound theoretical foundation that the factors are related.

7.3 Reliability

Reliability is one of the most basic psychometric properties of an instrument. It is the measure of consistency and reproducibility of an instrument. A reliable instrument must be internally consistent and produce stable and repeatable results. Reliability refers to homogeneity and the degree to which an instrument is free from random error (Bowling, 2005a).

Any measurement score includes two components: the real score and some degree of error. This error could be a random error (noise) and/or a systematic error (bias). Reliability refers to the degree to which a measurement represents the real score only, which is free from random error (Biases are examined in validation tests). Thus, reliability assures that any changes observed are due to actual variations in health levels as a result of an intervention and not due to problems of the instrument.

Reliability is not a fixed property of an instrument. In other words it is not a property that exists in a manicheistic sense that is either it fully exists or it does not exist at all. It is rather a property that any measure will have a certain degree of it, when applied to certain populations, under certain conditions. According to Streiner and Norman (2008):

“It is an interaction among the instrument, the specific group of people taking the test, and the situation”.

There are four types of reliability:

- internal consistency,
- test-retest reliability,
- inter-rater reliability and
- Parallel (alternative) forms reliability (SACMOT 2002).

All the above different types of reliability and their estimation methods are not necessarily mutually exclusive, nor do they necessarily lead to the same results. The various types of reliability are estimates of different characteristics that cannot be seen as equal (Streiner and Norman, 2008). It is almost certain that each method will

result in a different value for reliability. Usually test-retest and inter-rater reliability estimates will be lower in value than internal consistency. This is because, contrary to the methods calculating internal consistency, they involve measurement at different times or by different raters. Nevertheless, Streiner and Norman's warning should be remembered that internal consistency, the most commonly used type of reliability, is not in itself reliable and should be treated with care, because it ignores potentially important sources of variation that may occur over time (*ibid.*).

Furthermore, no type of reliability can cover all the possible sources of variance, as each one of them identifies and quantifies only one source of error variance (*ibid.*). However, each form of reliability should be examined on its own and any attempt to produce an average index by combining different types of reliability does not make any sense. Thus, more than one type should be used in the same evaluation project. Also, it should be remembered that reliability is not a built-in property of an instrument and should be examined often within a range of clinical and organisational contexts (Sheldon, 1993). The general idea, applying to all types of reliability, is that the question of reliability is in its essence a question of correlation of the items. At this point internal consistency, which is considered as the most important type of reliability, will be discussed.

7.3.1 Internal consistency

In general, internal consistency is the extent to which tests or procedures assess the same characteristic, skill or quality. This is the case when items comprising a scale or a dimension relate only to this particular construct. By relating to this construct it means that all of the items constituting the measure are measuring the same thing. Items that measure the same thing correlate with the other items in the measure (Howitt-Cramer, 2005). Four methods are used for internal consistency assessment to estimate: the split-half reliability; alpha reliability (Cronbach's α); item-item correlation; and item-total correlation. Cronbach's α and item-total correlation were used for the reliability assessment of the Greek instrument.

7.3.1.1 Alpha reliability (Cronbach's α)

Alpha reliability is an improvement of split-half reliability. It estimates the average of all possible correlations between the items of the scale. It is mathematically equivalent to calculating all the possible split-half reliabilities, by calculating all the possible combinations of items and estimating the average. Alpha reliability is also called Cronbach's α and it is the most common form of internal consistency.

“The α is basically the ratio of the sum of the covariances among the components of the linear combination (items), which estimates true variance, to the sum of all elements in the variance-covariance matrix of measures, which equals the observed variance” (Nunnally-Bernstein, 1994).

The general rule is that the higher the Cronbach's α , the higher the internal consistency. There are no universally accepted minimum-maximum levels of alpha. First, there are differences depending on the type of assessment one wants to make i.e. individual or group comparisons. For group comparisons, these levels are considered to be 0.70 -0.90 (Fitzpatrick et al. 1998), although Streiner and Norman (2008) clearly state that internal consistency should exceed 0.80.

7.3.1.2 Item-total correlation

After the item-item correlation is estimated, the total score of the items is used as another variable. Each item is then correlated with this new variable (the total score), giving the level of correlation between each item and the total. The item-total correlation measures the homogeneity of the scale. According to a “rule of thumb”, each item's correlation with the remainder of the scale should be ≥ 0.20 (Streiner – Norman, 2008; Fitzpatrick *et al.*, 1998).

7.4 Validity

After the examination of the importance of reliability as a psychometric property of an instrument, one should examine the other most important property, that of validity. This is necessary, because an instrument might be reliable but not valid. Of

course, an instrument cannot be valid without being reliable. Thus, reliability is a necessary but not sufficient condition for validity.

As it has already been said, reliability is the degree to which an instrument measures a specific concept. Validity on the other hand refers to the degree to which an instrument measures the specific concept that it purports to measure. Validity, like reliability, is not a manicheistic property (all-or-none) of a measure but it is a matter of degree. Thus, the keyword in validity is the word “*degree*” (Nunnally and Bernstein, 1994).

There are four types of validity: predictive validity, concurrent validity, content validity and construct validity. The first two can be combined and considered together as criterion-oriented validity (Cronbach – Meehl, 1955). The final division into three types of validity are established in literature as the “trinitarian” view of validity or the three Cs: Content, Criterion and Construct validity (Streiner-Norman, 2008).

7.4.1 Content Validity

Content Validity refers to the extent to which the content of an instrument appears logically to examine and comprehensively include the full scope of the characteristic or domain it is intended to measure (Bowling, 2005a). Content validity depends to a great extent on established previous theory and research. It is obtained from an examination of the items of a questionnaire to judge whether it taps the range of topics it claims to measure and it is assessed by judgements made by a panel of experts, usually the instrument developers (Hyland, 1992: 44). Patient’s involvement in this development process should be considered as a prerequisite, as it helps the experts to formulate the content of the instrument, but in some cases developers do not follow this widely accepted view.

The fact that content validity depends on experts’ judgements makes it unique compared with the other two basic types of validity i.e. the criterion and construct

validity. In contrast with the other two, content validity, as a qualitative judgement, is independent from test scores, or comparisons with other measures results, or changes after some kind of intervention.

Also, it should be mentioned that these instruments intend to measure quality of life, which is not a highly developed theoretical construct. Thus, developer's claims about the content validity of an instrument should not be taken in any way as an oracle (Bowling, 1995b).

7.4.2 Face validity

Face validity is concerned with how a measure or procedure appears i.e. how well designed the instrument looks or how reliable seems to be in gaining the information needed. Face validity is a superficial and the most value-judgement based type of validity. It is not in any way a technical type of validity. Moreover, it is not based on any theory or supported by any research, as the content validity, but on the developers' view about the test's appearance, design and capability to gain the information it purports to obtain. Despite the fact that face validity is a superficial form of validity it is widely accepted in literature as a form of validity.

Face validity should not be confused with content validity. It should rather be considered as the informal evaluation of apparent validity by the test users (Hyland, 1993). A practical way to distinguish the two is by thinking that content validity is concerned with the items of an instrument before the instrument is constructed. Face validity is concerned with the items after the construction of the instrument (Nunnally and Bernstein, 1994; Fayers and Machin, 2007).

It is in this sense, that Nunnally and Bernstein (*ibid.*) argued that face validity could be considered as “*one limited aspect of content validity*”, dealing with the final inspection of an instrument in order to ensure that the initial plans have been transformed into a new completed instrument. Nevertheless, Nunnally and Bernstein accept that by adjusting the face of an instrument to the terminology or jargon of the

target group could play an important indirect role in the construction and use of predictor instruments. However, even if one accepts the Nunnally-Bernstein view that face validity is part of content validity, these two types differ in essence and should not be confused.

The controversy about face validity goes even further, to the extent that serious doubts have been expressed as to whether face validity is validity. Downing and Haladyna (2004) argue that:

“...superficial qualities ... may represent an essential characteristic of the assessment but it is not validity... The appearance of validity is not validity; appearance is not scientific evidence, derived from hypothesis and theory, supported or unsupported... by empirical data and formed into logical arguments.”

On the other hand face validity is considered by other writers to be very important and lack of this property might cancel the instrument *per se*. Gill and Feinstein (1994) raising the question of:

“...whether the academic psychometric principles, although perhaps elegant statistically, are satisfactory for the clinical goal of indicating what clinicians and patients perceive as quality of life”,
concluded that:

“Many published measurements of quality of life seem clinically inappropriate because they have poor face validity”.

Care should be taken therefore in treating face validity as a separate psychometric property, but it should not be considered as something negligible when assessing an instrument.

7.4.3 Criterion Validity

Criterion validity is the correlation of a scale with some other measure used as criterion. It is used to demonstrate the accuracy of a measure by comparing it with another one which has been used and accepted to be valid. This other measure ideally acts as a “gold standard” (Streiner-Norman, 2008).

Criterion validity is determined by the degree of association between the instrument under examination and the criterion. This means that the criterion in a validation

process has to be accepted as “*given*”. This in turn means that this criterion has to be appropriate. At this point two problems arise: First, what is ‘appropriate’ and second, the so-called “*criterion problem*”, the problem of deciding what exactly should be measured. There are no simple answers to these problems.

It should also be noted that these problems represent a semantic differential between criterion and construct validity, analysed below. Construct validity is not tied to a criterion and the criterion is not “*given*”. A construct validation allows the evaluation of both the nominal predictor and the nominal criterion at the same time. This is the reason, according to Nunnally and Bernstein (1994), why criterion validity is direct, simple but limited in scientific generalisation and in real sense limited in its applicability.

Criterion validity can be examined under two different forms. The “concurrent” validity and “predictive” validity, depending on the existence of the criterion at the moment of the test or it will occur at some time in the future.

Concurrent validity is the corroboration that an instrument is measuring what it purports to measure against a criterion measure. The two measures should be administered at the same time (Bowling, 2005c). Predictive validity is the ability of a measure to predict future differences in key variables in the expected direction. The criterion in this case is unavailable until sometime in the future (*ibid*).

Predictive validity can also take the form of *discriminative* validity. This type of validity should not be confused with *discriminant* validity, which is a type of construct validity. Discriminative validity refers to whether a scale is able to differentiate between two groups with different traits (Streiner and Norman, 2008). It is based on the hypothesis that certain groups of patients are supposed to score differently than other groups (Fayers and Hand, 2002). An instrument is valid, when the scores of different groups, on the scales measured, are different. It is assessed by comparing group mean scores, using the same instrument. The scores should appear significant differences, or prove the hypothesized ones. In this sense known groups comparisons is a combination of a validity test and a form of sensitivity assessment (Fayers and Machin, 2007).

The notion of discriminative validity can be found under various terms. Streiner and Norman (2008) refer to it as “extreme groups” validity. In Lamping’s evaluation studies the term “known groups” appears for the same notion (Lamping *et al.*, 2002; Smith *et al.*, 2005; Cano *et al.*, 2006). The term “criterion groups validity” is also found in literature as synonymous (Todd and Bradley, 1994).

7.4.4 Construct validity

Construct validity is the extent to which an instrument tests the hypothesis or theory it is measuring (Bowling, 2005a). It has already been mentioned that QoL instruments measure “hypothetical constructs”. As such these attributes are not operationally defined and they cannot be directly observable and quantified (Cronbach and Meehl, 1955). However, these constructs despite the fact that they are “hypothetical” have an ontological status on their own that is they exist independently of their measurements (Hyland, 1993).

As mentioned in the introduction a construct is a ‘mini theory’. To explain what a theory is and how it works one could borrow some of Milton Friedman’s thoughts from the methodology of economics:

“A theory is a body of substantive hypotheses and has to be judged by its predictive power for the class of phenomena which it is intended to ‘explain’. Only factual evidence can show whether it is ‘right’ or ‘wrong’ ... the only relevant test of the «validity» of a hypothesis is comparison of its prediction with experience” (Friedman, 1953).

When an instrument is designed, the first step is to specify the theoretical concept that is the construct that it intends to measure. Construct validity assumes the existence of a construct. According to Cronbach and Meehl (1955), this construct is:

“... some postulated attribute of people assumed to be reflected in test performance. In test validation the attribute about which we make statements in interpreting a test is a construct”.

The designers have to form some hypotheses about the constructs the instrument purports to measure, as well as its theoretical relationships with other similar constructs or variables. Hyland (1993) made an interesting distinction between QoL

and these constructs. He argued that quality of life is not a single construct but rather several causally connected ones. He further argued that definitions of health or QoL are not the same as constructs. Thus, these definitions provide a useful basis for establishing content validity, but provide little information about the construct as such.

Therefore, construct validation of an instrument is the process that seeks agreement between these theoretical concepts, the postulated attributes, and the empirical evidence that occurred from its administration. In this sense construct validity estimates the extent to which an instrument is measuring qualities that it is intended to measure.

This is succeeded by comparing the scores of the instrument with the scores of other instruments or variables. Construct validation is a three phase procedure. In the first phase, certain hypotheses about the relationship of the instrument with other scales have to be determined. In the second phase, the empirical relationships between the measures must be assessed. Lastly, the empirical evidence (the experience according to Friedman) must be interpreted in terms of how it clarifies the construct validity of the instrument that is tested.

Certain problems arise during this procedure. First of all, a new measure is created to measure certain constructs in a different manner and not to replicate another instrument. Therefore, the two instruments should not be perfectly correlated. The extent to which the measures should correlate is another problem, as instrument developers do not explain why certain correlation scores that occur from the tests are satisfactory and show adequate construct validity (McDowell, 2006). Not explaining the correlation scores is only part of the problem. In most cases writers do not give any theoretical reasoning why they expect the certain type of association. It could be argued by a new comer to the field, that sometimes some hypotheses are made just to justify the results.

Construct validity is different from content and criterion validity. But their differences are only methodological. Construct and criterion validity differ in how directly they address properties of the instrument. However, despite the direct or

indirect approach to the issue, validity still addresses two properties: first the ability of the instrument to measure what it purports to measure and second its suitability for the pre-defined purpose (Williams and Naylor, 1992).

Conceptually construct validity is the same with all other types of validity. Streiner-Norman (*op.cit.*), argue that conceptually all three types of validity are the same. They extend their argument even further, quoting Guion's argument that construct validity is the basic meaning of validity and any other type is basically some form of construct validity. In this sense McDowell (2006) considers criterion validity simply as a "subcategory" of construct validity.

Methodologically, construct validity differs from the other types of validity in various ways. First, other types of validity, such as content and criterion, can be assessed with only one study. Construct validity is an on-going process, of learning more about the instrument, making new predictions and test them.

Second, with construct validity we test both theory and the instrument at the same time. If either or both are wrong the instrument is useless. In such a case, it is obvious that more than one test is needed to identify the source of the problem.

Finally, both theory and the scale could be right, but the experiment is wrong. Again it is impossible to spot the cause of the problem in one single test (Streiner and Norman, 2008).

Construct validity can be divided into two categories: "Convergent" and "Discriminant" validity.

Convergent validity is the extent to which measures theoretically purport to measure the same topic correlate (Bowling, 2005b). If the scores of these measures do not correlate there should be a problem either with the new measure or the theory or even its autonomic sensitivity. Again the measures should not be highly correlated because this indicates that the measures are almost identical (Streiner and Norman, 2008). Correlations between measures that theoretically measure the same attribute should range between 0.40 – 0.80. Correlations lower than 0.40 indicate either an

unacceptable low reliability of one measure or that the measures are measuring different phenomena (*ibid*).

Discriminant or divergent validity on the other hand indicates that the scale should not correlate with dissimilar or unrelated variables (Bowling, 2001; Streiner and Norman 2008). If such a correlation exists either the theory or the scale itself might be wrong. Of course, a novel instrument should have *de jure* discriminant validity in the sense that it measures something different from existing methods (Nunnally and Bernstein, 1994).

Finally, taking into consideration that a measure taps various dimensions of quality of life, one could consider that convergent and discriminant validity represent the two extremes in a continuum of associations between the dimensions of QoL (Fayers and Machin, 2007).

7.4.5 A summary for validity

Having discussed the various types of validity at least three points should be mentioned:

First, the validity of an instrument concerns the use to which the instrument purports to measure and not the instrument itself. Measures are often valid for one use but not for another (Nunnally and Bernstein, 1994). This is true even in cases where a disease-specific instrument is used for different groups of the same disease such as type 1 and type 2 diabetes patients. As Bradley (1996) argued “*the psychometric properties cannot be assumed to travel well*”. A typical example of this, concerning this review, is the use of the DQOL, which was designed for assessing QoL of people with type 1 diabetes. Its use with type 2 diabetes patients proved that its psychometric properties were less satisfactory.

Second, even if validity is seen as a property of an instrument’s it is not an ‘all-or-none’ property, but a matter of degree (Nunnally- Bernstein, 1994).

Third, validity is not a ‘once and for all’ attained property of an instrument. Due to the very nature of the (hypothetical) constructs the validation process should consist of learning more about the construct, taking into consideration any new theories, making new predictions or hypotheses and testing them all together (Streiner-Norman, 2008). In other words, the on-going validation process is something like accumulating validity in a construct.

7.5 Responsiveness – Sensitivity to Change

When one first approaches the concept of responsiveness one cannot avoid its association with one of Einstein’s anecdotes. During the period of the turmoil about the relativity theory, in the course of an examination, by mistake or on purpose, he handed out the previous year’s examination paper. His aids informed him that “these were last year’s questions”. “Yes”, answered the Professor, “but this years’ answers are different”. Likewise, responsiveness tries to detect different (new) answers to the same problem.

By reviewing the literature, about QoL instruments, one can easily reach the conclusion that responsiveness is an underestimated property by the vast majority of measures developers. Responsiveness is the ability of an instrument to detect changes. Changes always occur in different parameters during the course of time. In this respect responsiveness might be the most important property when the use of an evaluative instrument is needed. An evaluative instrument, according to the Guyatt *et al.* (1992) methodological framework for assessing health indices, is an instrument designed to detect longitudinal differences within people over time.

Responsiveness is probably the most ambiguous psychometric property. It embodies most of the problems mentioned in previous pages. First of all there is no unanimously accepted definition of responsiveness. Twenty-five different definitions have been found in literature grouped under 3 categories: The first group defines responsiveness as the ability to detect change in general; the second defines it as the ability to detect clinically important change; the third group defines

responsiveness as the ability to detect real changes in the concept being measured (Terwee *et al.* 2003).

Many writers use the terms *responsiveness* and *sensitivity to change* interchangeably. Others argue that the two are different and there should be a clear distinction between them. Sensitivity to change is the property defined by the first group that is to detect changes in general, while responsiveness deals with clinically important changes (Liang, 2000). In this respect, Liang argues, sensitivity to change is a necessary but insufficient condition for responsiveness.

The very existence of responsiveness as a distinguishable property is controversial. Some writers believe that there is a conceptual distinction between validity and responsiveness. Thus, they should be treated as two distinct properties when assessing an instrument (Guyatt *et al.*, 1989).

Other writers consider the distinction between responsiveness and validity as artificial. They argue that this is result of the false view that dichotomises the instruments as valid and not valid, failing to recognise that instruments are valid to varying degrees (Hays and Hadorn, 1992). Liang (*op.cit*) argues that responsiveness is equivalent to longitudinal construct validity i.e. the ability of an instrument to measure a clinically meaningful change. Terwee *et al.* (2003) agree with Liang's view and think of responsiveness as an indication of a measure's construct validity or a facet of it, i.e. longitudinal validity. Last, Streiner and Norman (2008) agree with the view that conceptually responsiveness is an aspect of validation, but it is most akin to criterion validity, i.e. whether the change detected by the test under validation correlates with the change as measured by another measure.

A study published in 2005 by Lindeboom *et al.* provided some empirical evidence supporting the above theoretical views. They concluded that responsiveness is not a separate psychometric property of health scales and that the internal consistency coefficient reflects an instrument's sensitivity to change over time. However, this view was contradicted by another study, claiming that internal consistency reliability is a poor predictor of responsiveness (Puhan *et al.* 2005).

Due to the conceptual interrelation that exists between responsiveness and validity, in this review, responsiveness will be reported separately whenever it is formally assessed, but under the heading of validity.

Chapter 8: Selection of Diabetes-specific Quality of Life Instrument for the Greek Population

8.1 Introduction

This chapter describes how diabetes-specific QoL measures were identified and reviewed. The review is focused at the identification of diabetes-related QoL measures and the selection of the most appropriate for this research instrument. Eleven diabetes-specific quality of life measures were identified and critically reviewed to find the most suitable to be used for this study. This task contained various difficulties, which mainly originated from the nature of the instruments used to measure a concept such as quality of life. The chapter also describes the method and the search strategy used to locate and retrieve references from electronic resources, as well as other sources used for data extraction, and reports the inclusion criteria.

The method and the format used for the review was influenced mainly by the instructions given by the Scientific Advisory Committee of the Medical Outcomes Trust (SACMOT, 2002) and other previous reviews (Garraat et al., 2002b; Fitzpatrick et al., 2006). A very brief account for each instruments' properties is given in this chapter referring to the background, conceptual-measurement model, reliability, validity and responsiveness, burden and acceptability, and any alternative forms or translations. Also, a brief critical summary of each instrument is given, including comments about strengths and weaknesses and a conclusion about the use of each particular measure. Four tables are included concerning the description, details about the conceptual and measurement models of the instruments, the tests that have taken place for each one of them, as well as their psychometric properties. At the end of the chapter a detailed account of the criteria for the selection of an instrument is given, as well as documentation justifying the final selection. However, a comprehensive and expanded version of the critique of individual measures is given

in Appendix A with details of the statistical methods used for the instruments' assessment, as well as the universally accepted levels, if any, against which a property should be compared. As there are no gold-standards for this, references to authorities in the relevant field have been made. The terms “heuristic” and “rule of the thumb” could not be avoided. However, one should bear in mind that “*heuristic is a way of thinking about a topic which is convenient even if not absolutely true*” (Darlington, 2006).

8.2 Search strategy

8.2.1 Aim

The aim of the search strategy was to identify diabetes-related quality of life instruments. A prerequisite for this search was to locate references concerning:

- Concepts such as QoL, health status, HRQoL;
- The measurement of QoL and HRQoL;
- The development and assessment of diabetes-specific instruments.

The first problem faced at this stage was to define quality of life, in order to avoid retrieving articles concerning other aspects of diabetes. Finding an acceptable and operationally suitable definition for this study was a complicated and multi parametric issue.

A good background had to be obtained before the work started. The theoretical background was obtained by reviewing the relevant literature. Bowling's four books (1995a; 2001; 2005a; 2005c; 2005e) have been used as the basis and the starting point of this work. Many topics on the instrument development process, including the psychometric validation, have been clarified by referring initially to the first edition of Streiner and Norman's book on Health Measurement Scales (1989) and later to the more complete 2008 edition. Nunnally and Bernstein's book (1994) was also of great help in clarifying areas of psychometric theory.

Reviews were also used to identify instruments. For example, the review of Garratt *et al.* (2000), of diabetes patient-reported health instruments reported studies up to 1999. Thus, some instruments and especially their subsequent validation studies were out of its reach.

Some useful but very brief synoptic reviews appeared more recently. Garratt *et al.* (2002) published a short version of the 2000 review for 9 instruments and Watkins and Connell reviewed 12 instruments in 2004. The more up-to-date work of the Patient-reported Health Instruments Group (Fitzpatrick *et al.* 2006) also served as a guide for this work. This review drew substantially to the Garratt *et al.* work and examined six diabetes-specific instruments.

The structure of my review might cause some misunderstanding. After a long period of trial and error the final result is a synthesis of proposals found in the literature, mixed with a degree of improvisation that I thought would be helpful for this particular work. The subheadings of this review should be considered only as a methodological convenience and by no means as a classification and assessment of independent properties. The underlying concept of the analysis is that there are no clear cut boundaries within the properties of an instrument. Thus, an attempt has been made in the comments section, to tackle the problem in a holistic manner, treating the properties as a continuum, and aiming to decide in the end about the validity of the instrument as a whole.

8.2.2 The electronic search

The electronic search followed these steps:

- First, it was necessary to decide the type of articles to be searched;
- Second, the inclusion criteria should be decided. This task would help before the beginning of the electronic search to identify key words, and after the search in accepting or rejecting articles and their corresponding instruments;

- Third, the design of the search strategy;
- Fourth, to find the most relevant databases and choose among them.

8.2.2.1 Inclusion criteria

In order to search the literature a series of inclusion criteria had to be decided for the selection of articles on diabetes and quality of life. To this end the following criteria have been used:

- The article should refer to a patient-reported or patient-assessed diabetes measure;
- The article should refer to a measure that is developed or translated into the English language. A thorough investigation of the Greek literature proved that there is no diabetes-specific quality of life instrument either developed in or translated into Greek;
- The measure should be characterised by its developers as assessing diabetes-related quality of life. To overcome the difficulties regarding the existing conceptual differences described elsewhere, instruments that used the term health status have been included;
- Articles that described measures addressing topics wider than QoL, but containing and assessing areas or dimensions of QoL were included;
- The measures should have been assessed at least once for its psychometric properties with adult patients, with published results concerning methodology and measurement issues;
- The measures should be referring to adults.

The following electronic bibliographic databases were searched using the Wolters Kluwer – Health Ovid SP software provided by the UCL Library Services:

- AMED. The Allied and Complementary Medicine Database, Health Care Information Service, the British Library;
- EMBASE. The Excerpta Medica Database, Elsevier;

- HaPI. Health and Psychosocial Instruments Database, Behavioural Measurement Database Services;
- MEDLINE. The United States National Library of Medicine. Electronic counterpart of *index Medicus*;
- PsycINFO. The American Psychological Association.

The search started by collecting keywords from books and articles in a step-by-step procedure. The search terms in the beginning were the word “diabet*” combined with the Boolean operator “and” with keywords indicating either quality of life or measure or questionnaire. The results showed hundreds of thousands of relevant articles. Truncation was performed by using a second “and” with words indicating the development or assessment of instruments. This included many articles concerning instruments dealing with topics other than QoL in diabetes (adherence, education etc.).

The first electronic search was performed in December 2007 and it continued under different strategies throughout 2008. The strategy that evolved was not considered as final and the search process was updated during the study.

The search strategy was as follows:

((Diabet and (Index or indices or instrument* or measure* or questionnaire* or profile* or scale* or score* or status or survey or appraisal or HRQOL or HRQL or QOL or quality of life or quality-of-life) and (develop* or assess* or evaluat* or stud* or review or investigat* or appraisal or valid* or reliability or psychometric* or propert* or responsive*))).m_titl.*

The search in the five databases retrieved 2020 articles. Then, two limits were introduced: Articles should be in English and published between 1976 and 2009. The starting year was chosen because it was the year that the term “Quality of Life” was first introduced in “Index Medicus”.

Having examined the results of the electronic search as well as the relevant literature a list of instruments was created. A new search was performed including the names of the instruments. The final search strategy was:

((((Diabet and (Index or indices or instrument* or measure* or questionnaire* or profile* or scale* or score* or status or survey or appraisal or HRQOL or HRQL or QOL or quality of life or quality-of-life) and (develop* or assess* or evaluat* or*

stud or review or investigat* or appraisal or valid* or reliability or psychometric* or propert* or responsive* or status or HRQOL or HRQL or QOL or quality of life or quality-of-life)) or ADS or Appraisal of Diabetes Scale or ADDQOL or Audit of Diabetes Dependent Quality of Life or DCP or Diabetes Care Profile or DHP or Diabetes Health Profile or DHS or Diabetes Health Status or DQOL or Diabetes Quality of Life or DSQOLS or Diabetes Specific Quality of Life Scale or D-39 or Diabetes-39 or DDS or Diabetes Distress Scale or DIMS or Diabetes Impact Measurement Scales or PAID or Problem Areas in Diabetes or DQLCTQ or DQLCTQ-R or Diabetes Quality of Life Clinical Trial Questionnaire or LQD or Quality of Life with Diabetes Questionnaire) and (develop* or assess* or evaluat* or stud* or review or valid* or reliability or psychometric* or propert* or responsive*)).m_titl.*

8.2.3 Other Sources:

The reference lists of the books and articles which emerged from the electronic search were checked and revealed publications that had not been identified by the electronic search. Also, a manual search of four journals was performed in July 2009. These journals are:

- Quality of Life Research;
- Diabetes Care;
- Health and Quality of Life Outcomes;
- Applied Research in Quality of Life.

Last, already published reviews were used for additional references. The work of Fitzpatrick *et al.* (1998) and Lohr *et al.* of the SACMOT (2002) and Fitzpatrick *et al.* (2006) were of great help not only for deciding on the review criteria, but also on the structure of the review as well. However, the final inclusion-exclusion decision was to a great extent a matter of personal value judgement.

8.2.4 Results

Out of the 2020 records initially located 1088 records remained when the duplicates and the non-English language papers were removed. 995 records were screened and

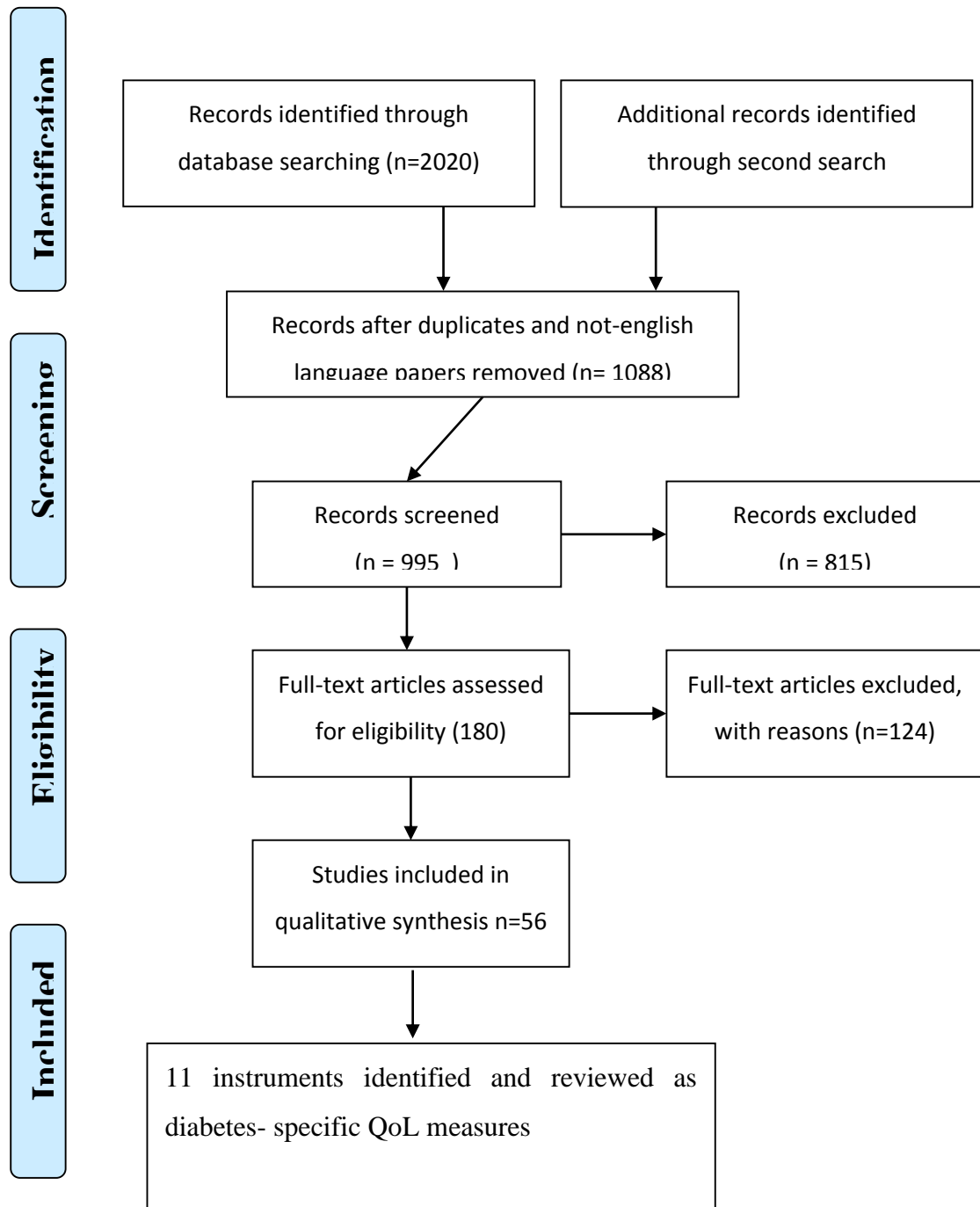
after examining their titles and/or abstracts another 815 were removed. The full texts of the remaining 180 were retrieved and assessed for eligibility and 124 of them were excluded as not meeting the inclusion criteria either because QoL did not represent a significant component in their structure, or because they did not have sufficient information about the development and evaluation of the instrument. The remaining 56 studies were included in qualitative as well as the quantitative synthesis of the review. Out of these 56 studies 11 instruments were identified and reviewed.

These instruments are:

- Appraisal of Diabetes Scale (ADS)
- Audit of Diabetes Dependent Quality of Life (ADDQoL)
- Diabetes Care Profile (DCP)
- Diabetes Health Profile (DHP)
- Diabetes Impact Measurement Scale (DIMS)
- Diabetes Quality of Life (DQoL)
- Diabetes QoL Clinical Trial Questionnaire (DQOLCTQ)
- Diabetes-Specific Quality-of-Life Scale (DSQoLS)
- Diabetes – 39 (D-39)
- Problems Areas In Diabetes (PAID)
- Diabetes Distress Scale (DDS)

The flowchart of the search is presented in Figure 3.

Figure 3: Flowchart of search strategy (Moher *et al.* 2009)



8.3 Instrument Review

8.3.1 Introduction

The structure of this review was based mainly on the criteria developed by the Scientific Advisory Committee of the Medical Outcomes Trust (SACMOT, 2002). A subheading concerning the background of the instrument was added in the beginning, as well as some critical comments in the end. Thus, the structure of the review concerning each instrument contains the following subheadings:

- Background;
- Conceptual and Measurement model;
- Reliability;
- Validity and Responsiveness;
- Acceptability;
- Alternative forms;
- Cultural and Language Adaptations;
- Comments.

Four tables are included in the review. Table 1 summarises the description of the instrument providing information about the type of diabetes that the instrument assesses, the name of the developer and country of origin, the original language, time of administration, its main aim, the content as well as any existing translations. Table 2 contains information about the conceptual and measurement models of the instruments. A brief account of the underlying concepts is given, the item generation and item reduction process, the response format, and the scoring method. Table 3 summarises the tests that the instruments have undergone and table 4 gives details about the results of the tests concerning their psychometric properties in the form of reliability, validity and responsiveness.

Table 1: Description of instruments

Instrument	Diabetes type	Developer	Country/ Year	Original Language	Time needed	Aim	Content	Translations
Appraisal of Diabetes Scale	1 & 2	Carey M.P et al	USA	English (USA)	≤ 5 min	To assess patients' appraisal of diabetes	Single index, 7 items distress, control (2), uncertainty, prediction about the future, coping and effect on life goals	None
Audit of Diabetes Dependent Quality of Life	1 & 2	C.Bradley	UK	English (UK)	10 min	To measure how the individual perceive and rate the impact of DM on all applicable aspects of life, together with the perceived importance of each domain	Single Index Diabetes impact: 19 domain-specific: leisure activities, working life, travelling, holidays, physical activity, family life, friendships-social life, personal relationships, sexual life, physical appearance, self confidence, motivation, people's reaction, future worries, financial situation, living conditions, dependence on others, freedom to eat, freedom to drink. + 2 overview items: present QoL, diabetes & QoL.	French (for France, Canada), German, Italian, Polish, Spanish (for Spain, Mexico, USA),English (for USA, Australia, Canada, India, Singapore),Hindi (+for UK), Portuguese for Brazil, Chinese, Cantonese for Hong Kong, Hungarian, Malay, Punjabi (+for UK), Slovak, Greek.

Table 1: Continued

Instrument	Diabetes Type	Developer	Country/Year	Original Language	Time needed	Aim	Content	Translations
Diabetes Care Profile	1 &2	J. Fitzgerald	USA	English (USA)	30-40 min	To measure the social & psychological factors in patient's adjustment to DM and its treatment	234 items in total.16 sub-scales measuring: Control problems, social –personal factors, positive, negative attitude, self-care ability, care importance, self-care and diet adherence, medical monitoring and exercise barriers, understanding mgt practice, long -term care benefits, support attitudes, support and needs.	Chinese
Diabetes Health Profile	1	Meadows K	UK/1996	English (UK)	-	To identify psychosocial dysfunctioning of adult IDDM	Total 32 items. 3 subscales: psycho logical distress (14), barriers to activity (13), disinhibited eating (5)	14 in total. Danish, Dutch, English (Au, SA), Flemish, French, German (+CH), Hebrew, Italian, Polish, Russian, Spanish, Urdu
Diabetes Impact Measurement Scales	2 1&2	Meadows K S Hammond	UK/2000 USA/1992	English (USA)	15-20	To measure longitudinal change in patients to quantitate treatment benefits in cl. Trials	44 items; 4 domains Symptoms: 17 Well-being: 11 Morale: 11 Social role: 5	Chinese (Mandarin) French, Italian

Table 1: continued

Instrument	Diabetes Type	Developer	Country/ Year	Original Language	Time needed	Aim	Content	Translations
Diabetes QoL Clinical Trial Questionnaire	1&2	W. Shen J. Kotsanos	USA (mainly)	English (USA) + German French (before validation)		The development of a reliable instr. For use in multinational clinical trials for both types of diabetes	Rev: 57 items, 8 domains. Physical function, energy/fatigue, health distress, mental health, satisfaction, treatment satisfaction, flexibility and frequency of symptoms	German , French
Diabetes-Specific Quality-Of Life Scale	1	U. Bott	Germany	German	10-20	To measure QoL of patients with T1 diabetes and assess preference-weighted treatment satisfaction	39 items 6 scales: Social relations 11, leisure time flexibility 6, physical complaints 8, worries about future 5, diet restr. 5, daily hassles 4	English
Diabetes-39	1&2	G. Boyer JA Earp	USA 1997	English (USA)	NR	To assess the QoL of people with diabetes	39 items–5domains Energy-mobility 15 control 12, anxiety-worry4, social-peer burden 5, sexual functioning 3.	Spanish for Mexico
Problem Areas In Diabetes	1&2	W Polonsky	USA 1995	English (USA)	3-5 min	To assess diabetes related emotional distress	Single index 20- items in areas: distress, anger, guilt worry, fear, depressed mood	Chinese, Chinese, Danish, Dutch, Finnish, German, Japanese, Portuguese (+for Brazil), Spanish, Chinese, Swedish

Table 1: continued

Diabetes Distress Scale	1&2	W Polonsky	USA 2005	English (USA)	NR	To assess diabetes related emotional distress	17 items-4 domains: Emotional burden 5, regimen distress 5, physician distress 4, inter-personal distress 3	-
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Table 2: Conceptual & measurement models

Instrument	Underlying construct	Item generation	Item Reduction Factor generation	Response format	Scoring method
Appraisal of Diabetes Scale	Lazarus & Folkman's theory of stress management. (stress: when pressure exceeds ones' ability to cope. Management: Factor & methods' identification for controlling the pressure)	Items adopted from Hammen – Mayol's Attribution Questionnaire, and research on appraisal processes.	PCA: 1 factor explaining 39% of total variance	5-point scale	Summated items produce a single index
Audit of Diabetes Dependent Quality of Life	Joyce's theory of patients' views & perception and the generation of domains of importance by them, as first applied in SEIQoL	No patient involvement SEIQoL's philosophy used for framework + design. Literature review, Health experts + existing instruments , in-depth interviews with 12 patients	FA . 18 items loading on 1 factor >0.50	impact: 5-point scale from -3 to +1 importance: from 0 to 3	Summated (items + importance) produce a single index
Diabetes Profile	Care Theory of adherence to various dimensions of diabetes regimens	DEP, HBM (perceived severity of disease, perceived susceptibility to complications, benefits and barriers to adherence). No patient involvement	FA and CFA	5-point scale	Score/scale = Mean score of total items

Table 2: continued

Instrument	Underlying construct	Item generation	Item Reduction Factor generation	Response format	Scoring method
Diabetes Health Profile	NR	Literature review, in-depth interviews with patients, existing instruments, discussions with experts 95 items in 5 constructs	2 consecutive tests on patients & PAF analyses. 1 st : 43 items remain, 3 factors 2 nd : 32 items remain, 3 factors explaining 33% of total variance. 3 rd test (2000): 3 factors expl. 40.3-45.6% of var.	4 point Likert scale 0: No impact 3: high impact	Summated scores for each subscale, producing scores 0-100 according to SF-36 formula
Diabetes Impact Measurement Scales	NR	Literature review, health status instruments SF-36, SIP AIMS, discussions with experts. No patient involvement Literature review, mental health - diabetes clinicians, nurses, and patients. Other instruments NR	PCA : 1 factor explaining 32% of total variance	0- 4 Likert 0: Low QoL 4: High QoL	subscale & total scores computed by adding individual item scores
Diabetes Quality Of Life	DCCT theory of intensive therapy of diabetes and glycaemic control		NR	5point Likert 1: Low QoL 5: High QoL	Summated scores to 0-100 scale
Diabetes QoL Clinical Trial Questionnaire	NR	Literature review, 30 patients Items drawn from SF-36, SF-20, the DQOL measure, The HFS, and 31 items newly developed by experts	3 consecutive stages 1 st : 293 items 2 nd : 142 items 3 rd : 57 items	5point Likert	Domains scores converted to 0 -- 100

Table 2: continued

Instrument	Underlying construct	Item generation	Item Reduction Factor generation	Response format	Scoring method
Diabetes Specific QOL Scale	NR	2 existing instruments in Germany, discussions with patients, health experts	PCA for 44 items resulted in 39-items, 6 factors. Factors confirmed by CFA	6-point Likert 1: Low QoL 6: High QoL	summated scores
Diabetes-39	NR	Literature review, interviews with diabetes clinicians, educators, and patients	3 consecutive stages 1 st : 93 items 2 nd :42 items 3 rd : 39 items	VAS 1-7 7:high impact	5-point Likert. 0= no problem-4 serious problem Conversion to 0-100= Item scores sum X 1.25
Problem Areas In Diabetes	NR	Literature review, discussions diabetes experts, interviews with patients	PCA: 1 factor explaining 52.4% of total variance	5 point Likert 1: High QoL 4: Low QoL	Score converted to 100. Item score sum X 1.25
Diabetes Distress Scale	NR	Revision of PAID, QSD-R, ATT-39 by diabetes experts and patients	EFA: 1 factor. Loading not reported.	6 point Likert 1: High QoL 6: Low QoL	NR

Table 3: Field tests: Study & Respondent characteristics

Instrument & Studies	Test Site	Mode of Admini stration	Diabetes Type	Sample Size	Gender (M)	Mean Age (M – F)	Treatment Regimen Tablets & Diet	Duration (years)
Appraisal of Diabetes Scale Carey et al (1991)	Veterans medical centre	interviews and postal		200	100%	58.4	34%	15
Audit of Diabetes Dependent Quality of Life a : Bradley et al (1999) b : Costa et al (2006) c : Kamarun Imran et al (2007) d : Wee et al (2006)	a1. Bromley a2. Cambridge b. Portugal c. Malaysia d. Singapore e. Greece		1&2 1&2 1 &2 2 1&2	a ₁ : 102 a ₂ : 52 b : 100 c : 288 d : 173	53.9% 53.8% 46% 61.1% 55.3%	61.60 52.38 61.3 52.7-51.1 52.0	67.5% 37.2% 73% 73% 64.8%	7.27 12.71 12 8.7 – 7.6 10.1
Diabetes Care Profile a : Fitzgerald, Davis et al ; (1996) b: Fitzgerald, Grupp et al; (2000) c. Anderson et al (1997)	All in Michigan a1. Community a2: Med. centre b: Various clinics c:Research centre	a1: interviews a2: postal b: interviews c: interviews	1&2 1&2 2 2	a ₁ : 440 a ₂ : 352 b: 672 c: 255	45% 40% 44.8% 45%	61 54 63.1 63.4	55% 33% 48% 64%	10 14 12.45 8.6
Diabetes Health Profile a: Meadows et al (1996) b: Godijn et al (1996) c: Whitty et al (1997) d: Meadows et al (2000)	UK 1outpatient clinic UK 54 outpatient clin UK 7 outpatient clin NL 1 outpatient clinic UK 6 diabetes clinic UK 1 diabetes centre DK 1 diabetes centre	postal postal postal postal postal	1 1 1 1 2 2 2	a ₁ : 239 a ₂ : 2239 a ₃ : 233 b : 99 c : 48 d _{UK} : 426 d _{DK} : 460	NR a ₂ : 51% a ₃ : 52% 48.5% 42.0% 57.0% 53.9%	40.85 39.80 51.46 61.20 NR 61.63 63.66	0 0 0 100% 100% 58.9% 80.7%	13.7 13.1 NA 8.5 NA NR NR

Table 3: continued

Instrument & studies	Test Site	Mode of Admini stration	Diabetes Type	Sample Size	Gender (M)	Mean Age (M – F)	Treatment Regimen Tablets & Diet	Duration (years)
Diabetes Measurement Scales a: Hammond – Aoki (1992) b: Li et al (2006)	Impact a : California b : Taiwan - China	interviews interviews	1&2 2	a: 130 b : 219	42% 35%	45 63.5	22% NR	11 8
Diabetes Quality Of Life	a:USA 21 diab centres b:Boston diab centre	interviews interviews	1 T1:48.25%,T2:53.75	190 240	60% 47%	28 T1:44T2:60	0 47%	8 T1:18.8,T2:12
Diabetes Quality of Life Clinical Trial Questionnaire J. Kotsanos	Various clinical trials in the USA, France, Germany & Canada.	interviews during various randomised clinical trials	1&2	942	56.6%	T1: 33.8 T2: 58.2		12.6
Diabetes-Specific Quality-Of Life Scale	Germany: Northrhine Primary care units	interviews	1	657	58%	36	0	18
Diabetes-39	a:Cary:diab. Centre b: Iowa: gen. practice c:Carolina outpatient hospital clinic	postal postal postal	T1:67.5%,T2:27% T1: 19%, T2:81% T1: 9.5%, T2:90%	516 165 262	45.5% 45% 36%	52.4 61.7 55.3	27% 44% 35%	14.2 11.5 10.1
Problem Areas In Diabetes	a:Joslin diab. Centre b:Joslin diab. Centre c: Dutch diab. Associ	interviews interviews Postal	T1:82.4% T2:17.6% T1:52.7% T2:47.3 T1:50.2% T2:47.6%	451 256 1472	0 40.7% 51%	36.4 52.3 51	0 14% 13.5%	15.9 15.1 16

Table 3: continued

Instrument & studies	Test Site	Mode of Admini stration	Diabetes Type	Sample Size	Gender (M)	Mean Age (M – F)	Treatment Regimen Tablets & Diet	Duration (years)
Diabetes Distress Scale	San Diego USA Boston Honolulu	interviews	T2: 83.3	683	52.3%	56.4	49.6%	12.8

Table 4: Field tests: Psychometric Properties of Diabetes-specific QoL Instruments

Instrument/Study	Reliability			Validity				
	Cronbach's a	Item total	Test-retest	Scale Analysis	Convergent/ Discriminant	Other variables	Known groups differences	Responsiveness
Appraisal of Diabetes Scale Carey et al 1991	0.73	0.281-0.589	1h-1w: .89 - .85	A single factor accounted for 39% of variance	PSI r:0 .39 -0 .58 DDHS r: 0.59 DHBQ-R r:0.31- 0.42 PSS r: 0 .49 DRAQ-R r: 0.17	HbA _{1c} r:0.18	NR	NR
Audit of Diabetes Dependent Quality of Life a : Bradley et al 1999 b : Costa et al 2006 c : Kamarun Imran et al 2007 d : Wee et al 2006 e : Bradley & Speight 2002	a: 0.84 b: 0.89 c: 0.94 d: 0.94 e: 0.92	a: 0.37-0.67 c: 0.51-0.78	- - c: 0-1w:0.81	All items loaded On one factor: a: >0 .40 b: >0 .43 c: >0 .52 d: >0 .40; explained 49.2% of variance e: > .51	Overview items of ADDQoL: QoL without D: 0.47 Present QoL: 0.31 Other instruments: NR	Hypoglycaemia: r: 0.32 Complications: r: 0.21	Greater impact of D for people: IDDM complications hypoglycaemia	NR
Diabetes Care Profile a: Fitzgerald et al 1996 a1: Community a2: Medical Centre b: Fitzgerald et al 2000 c: Cunningham et al 2005 c1: White- non Hispanic c2: Hispanic	a1: 0.60 - 0 .95 a2: 0.66 - 0 .94 b: c1: 0.63 - 0.95 c2: 0.54 -0.97	NR	NR	NR	a: SPS r: -0.34- 0.32 a: CESD r: -0.53-0.48 a:HSS r: -0.27-0.32 c1: BDI:-0.50- 0.45 c2: BDI:-0.53- 0.44 c1: DFBC: 0.30-0.24 c2: DFBC: -0.33-0.36	a:GHb: -0.33-0.21 b: c: GHb: -0.26-0.19	a&b: Insulin users report greater impact on social/ personal lives. b: Caucasians using insulin- the most negative to diabetes	NR
Diabetes Health Profile a: Meadows et al (1996) b : Godijn et al (1996) c : Whitty et al (1997) d : Meadows et al (2000)	a2: 0.77 - 0.86 a3: 0.80 - 0.85 d : 0.70 - 0.88	a: 0.47-0.75 d: >0.40 (except item 6)	NR	3 factors accounting for 33% of variance	a:HADS r=0.28-0.62 SF-36 r=0.17-0.68 b:SF-36 r=0.07-0.65	NR	Women score higher v men. Young patients worse scores	c: 2 scales assessed 6 weeks from baseline: SRM: Psychological distress 0.23 barriers to activity 0.02 (insignificant changes-scales no responsive)

Table 4: continued

Instrument/Study		Reliability			Validity				
		Cronbach's a	Item total	Test-retest	Scale Analysis	Convergent/ Discriminant	Other variables	Known groups differences	Responsiveness
Diabetes Impact Measurement Scales	a: Hammond, Aoki (1992) b : Li et al (2006)	a: .60- .85 -.94 b: .61- .86	NR	a: 1m: 0.61-0.78 (not traditional) b: 1-2 w:0.55-0.92	One factor account. for 32% of variance	a: DC(Pat):0.22-0 .55 DC(Clin):0.24-0.35 GW(Pat):0.27- 0.47 GW(CI):0.29-0.45	HbA _{1c} : negative correlation (.04 - .01) Age: pos cor/ed with well-being Sex: neg cor/ed with symptoms	Women reporting more Symptoms	NR
Diabetes Quality Of Life	a:Jacobson et al (1988) b:Parkerson et al (1993) c:Jacobson et al (1994)	a: 0.67-0.92 b: 0.52-0.88 c: 0.47-0.87	NR	a: 0.78-0.92	NR	SCL:0.40-0.60(total) ABS:0.25-0.57(total) PAIS:0.06-0.63 c:SF-36:-0.003 – 0.59	NR	Males: less impact, worries. Complications: greater impact. Insulin: greater impact, less worries. Married: less worries, better mental health. Age: mixed effects	NR
Diabetes Quality of Life Clinical Trial Questionnaire		0.53 - 0.8.89 DQLCTQ-R: 0.77-0.91	NR	n=50 ICC>0.70 except 2 domains(worry & stigma)	NR	NR	NR	T1 patients, males, with tight metabolic control, high-self perceived control = better QoL	Check of GHb 6 months-baseline. Health distress, mental health, satisfaction, and treat. satisfaction. Responsive to change
Diabetes-Specific Quality-Of Life Scale		0.70 – 0.88	NR	NR	6 factors explaining 50.1% of variance	Positive Well-being Scale (r: 0.35-0.53)	HbA _{1c} : negative correlations (0 - .24)	age: r=-0.01 -0.23 duration r=0.02-0.22 social status: r=0.24-0.04	NR

Table 4: continued

Instrument/Study			Reliability			Validity				
			Cronbach's a	Item total	Test-retest	Scale Analysis	Convergent/ Discriminant	Other variables	Known groups differences	Responsiveness
Diabetes-39 a :Iowa b : Carolina			a: 0.82-0.93 b:0.81-0.93 patients >75 years or <high school α:0.70	0.45-0.84	NR	5 factors explaining 90.4% of varianve	SF-36: a: 0.15-0.71 b:0.20-0.68 Overall QoL: a: 0.22-0.44 b:0.22-0.35 Diabetes severity: a:0.24-0.56 b:0.27-0.56	NR	comorbidity patients: and >75 years high on energy-mobility. Young pat: High on control, worry, social burden. Men: higher on sexual functioning. T1 higher than T2 for worry, control.	NR
Problem Areas In Diabetes			a: 0.95 b: 0.95 c: 0.93-0.95	a: 0.32-0.84 mean: 0.68	c:0.83 (66 days)	b:Single factor accounting for 52.4% of variance	STAI:0.61, GSI: 0.63 HFS-W 0.57, BULIT-R 0.61, SCI: 0.09-0.49	a:HbA _{1c} :.30 b: HbA _{1c} :.15-.34 c: s-r HbA _{1c} :.11	Type 1 higher distress than T2. Patients with hypoglycaemic, DKA episodes or mental health problems: higher distress	d: Data from 7 studies: Effect sizes ranging from 0.32 to 0.64. Half of results being moderate (>0.50). Low to moderate responsiveness
Diabetes Distress Scale			0.93	NR	NR	28-item v 17-item correlation r=0.99 17-tem mean subscale cor. r=0.82	CESD r = 0.56	Age r = -0.29 Cholest r = 0.20 HbA _{1c} = 0.01 meal planning r = 0.30	NR	NR

8.3.2 Brief Appraisal of Instruments

8.3.2.1 “Appraisal of Diabetes Scale” (ADS)

Background: Developed in the USA by M. Carey. First published in 1991.

Conceptual-Measurement model

Item generation: Previous questionnaires, research on appraisal, no patient involvement.

Items: 7 items: distress, control (2), uncertainty, prediction about the future, coping and effect on life goals.

Response format: 5-point scale.

Scoring method: Summated items producing a single index

Reliability: Cronbach’s α : acceptable but at the lowest level (0.73). Item-total: well above minimum (0.28-0.59). Test-retest: reliable over repeated administrations.

Validity and Responsiveness:

Validity: Convergent validity: tested against 5 other instruments with hypothesised correlations confirmed.

Responsiveness: Not assessed.

Burden & Acceptability

Completion time: < 5 min.

Acceptability: 78.5% for the 1-week retest.

Alternative forms: None.

Cultural and Language Adaptations: None.

Comments:

Strengths:

- Easy to administer;
- Moderate to good reliability.

Weaknesses:

- No patient involvement;
- Tested on males only – no evidence on psychometrics for women;
- Content validity not tested;
- Convergent validity hypotheses confirmed, but expected magnitude of correlation was not reported;

- Construct validity was not assessed.

Conclusion:

Deficiencies in the development process (no patient involvement), as well as in testing (male sample only) make the instrument unreliable.

8.3.2.2 “Audit of Diabetes Dependent Quality of Life” (ADDQoL)

Background: Developed in the UK by C. Bradley, first published in 1999.

Conceptual and Measurement model:

Item generation: based on Joyce’s theory concerning patient’s views, SEIQOL, previous research, health professionals and patients with diabetes.

Items: 19. Each item followed by importance rating. (leisure activities, working life, travelling, holidays, physical activity, family life, friendships-social life, personal relationships, sexual life, physical appearance, self-confidence, motivation, people’s reaction, future worries, financial situation, living conditions, dependence on others, freedom to eat, freedom to drink) + 2 global questions (Life without diabetes, overall QoL).

Response format: Items: 5-points scale. Importance rating: 4-point scale.

Reliability: Measured by Cronbach’s α , and item-total correlation: very good.

Validity and Responsiveness:

Validity: assessed only against the two global items. Low correlations (0.21 and 0.32) show that the measure provides good additional information.

Responsiveness: Not assessed.

Burden & Acceptability: Low acceptance rates in the initial two tests (47.7% and 71.8%).

Alternative forms: The ADDQoL-Teens for young people with Type 1 diabetes.

Cultural and Language Adaptations: 23 adaptations (the most translated measure).

Comments:

Strengths:

- Patient and health professional’s participation give evidence for content validity;

- The only diabetes-specific measure with importance rating;
- The only diabetes-specific measure with ‘non-applicable’ option;
- It allows positive responses, allowing for possible positive impact of the disease;
- It contains two global questions;
- It is the most translated measure, capable of international comparisons.

Weaknesses:

- Poor validity assessment (only against its global items);
- Small sample sizes in tests and one not representative (convenient);
- Low to moderate acceptability reported.

Conclusion: Its strengths outweigh its weaknesses. Also, the subsequent equivalence studies rectify to some extent these weaknesses. The best instrument reviewed for this project.

8.3.2.3 “Diabetes Care Profile” (DCF)

Background: Developed in the USA by J. Fitzgerald. First published in 1996

Conceptual-Measurement model

Aim: To measure social and psychological factors in patient’s adjustment to diabetes and its treatment.

Item generation: Previous questionnaires, no patient involvement.

Items: 234 - 16 subscales.

Response format: 5-point scale.

Scoring method: Score/scale or mean score of total items.

Reliability: Cronbach’s α : acceptable but at the lowest level for all but two subscales.

Validity and Responsiveness:

Validity: Tested for construct and concurrent validity against 5 different measures with good results.

Responsiveness: Not assessed.

Burden & Acceptability

Completion time: Authors report 30-40', which is unrealistic for 234 items.

Acceptability: Very low: 28.5% and 43.2%.

Alternative forms: Each subscale can be used as a short-form.

Cultural and Language Adaptations: None.

Comments:

Strengths:

- Evidence for good validity.

Weaknesses:

- No patient involvement during development;
- The length of the measure (234 items);
- Validity tested for only 4 out of 16 subscales;
- It does not cover the concept of QoL, according to the accepted definition;
- Low acceptability.

Conclusion: Too lengthy and unreliable as QoL measure and unreliable in its short-form.

8.3.2.4 “Diabetes Health Profile” (DHF)

Background: Developed in the UK by K. Meadows. First published in 1996.

Conceptual-Measurement model

Aim: To identify psychosocial dysfunctioning of adult Type 1 diabetes patients.

Item generation: Literature review, interviews with patients, existing instruments, health experts.

Items: 32 in 3 subscales: psychological distress, barriers to activity, disinhibited eating.

Response format: 4-point scale.

Scoring method: Summated scores for each scale.

Reliability: Cronbach's α : Moderate to good (0.70 – 0.88).

Validity and Responsiveness:

Validity: Evidence for face and content validity. Good convergent and discriminant validity.

Responsiveness: Not formally assessed. 2 subscales tested in a subsequent study failed to detect differences.

Burden & Acceptability

Completion time: Not reported.

Acceptability: Very good (79-86%).

Alternative forms: Instrument adapted for use with Type 2 patients containing 18 items with good reliability and validity.

Cultural and Language Adaptations: 14 languages (second most translated measure).

Comments:

Strengths:

- The only Type-specific diabetes instrument, thus reliable for clinical studies;
- Item generation process satisfies all relevant criteria;
- Good reliability (internal consistency), good validity in almost all its forms.

Weaknesses:

- As a Type-specific instrument is not suitable for general surveys;
- Relatively lengthy thus unsuitable if used in combination with a generic measure.

Conclusion:

Although a measure with good properties, its weaknesses make the DHP unsuitable for this research purpose.

8.3.2.5 “Diabetes Impact Measurement Scale” (DIMS)

Background: Developed in the USA by Hammond and Aoki. First published in 1992.

Conceptual-Measurement model

Aim: To measure longitudinal change in patients, in order to quantify treatment benefits in clinical trials.

Item generation: Literature review, health-status instruments, health experts, no patient involvement.

Items: 44 items in 4 domains (symptoms, well-being, morale, and social role).

Response format: 4-point scale and two visual analogue scales.

Scoring method: subscale and total score by adding individual item scores.

Reliability: *Cronbach's α :* Low, moderate and good (0.60 – 0.85) for the various subscales. *Test-retest* reliability was assessed but with undefined and different time-intervals, thus not conclusive.

Validity and Responsiveness:

Validity: Tested against global rating scales and clinical variables showing good correlations with symptoms of the disease, but insignificant ones with medical variables such as complications.

Responsiveness: Not assessed.

Burden & Acceptability

Completion time: 15-20'.

Acceptability: Not reported.

Alternative forms: None.

Cultural and Language Adaptations: 3

Comments:

Strengths:

- Evidence for reliability, but not for all subscales;
- Contradictory results for validity.

Weaknesses:

- No patient involvement in development;
- Poor interpretation of validity results;
- Some items provide little or no information, but nothing has been done to remove them.

Conclusion:

The measure needs further attention to overcome its shortcomings, but it seems abandoned by its developers.

8.3.2.6. “Diabetes Quality of Life” (DQoL)

Background: Developed in the USA by Jacobson in 1988. The first diabetes-specific measure.

Conceptual-Measurement model

Aim: To evaluate the burden of an intensive diabetes treatment regimen.

Item generation: Literature review, mental health & diabetes clinicians, nurses, and patients.

Items: 46 core items in 4 dimensions: treatment satisfaction, treat. Impact, D worry, social/ vocational worry.

Response format: 5-point scale.

Scoring method: Subscale and total scores computed by adding individual item scores.

Reliability: Cronbach's α : Contradictory results between tests and subscales ranging between unacceptable and high (0.47-0.92) with most subscales at a very low level. Good *test-retest* reliability.

Validity and Responsiveness:

Validity: Content & face validity supported for type 1 patients only. Good convergent validity, low discriminative validity. Doubts about the value of the DQoL as a diabetes-specific measure compared with generic ones.

Responsiveness: Not formally assessed. An indirect assessment showed unsatisfactory levels of responsiveness.

Burden & Acceptability

Completion time: Not reported.

Acceptability: Ranges between 77-91%.

Alternative forms: Short-form of 15 items: the DQOL Short-Form Clinical Inventory.

Cultural and Language Adaptations: French, Spanish, Chinese, and Turkish.

Comments:

Strengths:

- The most widely used diabetes-specific instrument, good for comparisons – first instrument in the field.

Weaknesses:

- Instrument designed for type-1. Its adaptation for type-2 not very successful;
- Low to unacceptable internal consistency;
- Item generation not adequately described and only with type-1 patients;

- Low levels of internal consistency;
- Lower performance compared with generic measures.

Conclusion:

A highly overvalued measure with serious structural deficiencies.

8.3.2.7. “Diabetes QoL Clinical Trial Questionnaire” (DQLCTQ)

Background: Developed in the USA, France, Germany, and Canada. First published in 1999.

Conceptual-Measurement model

Aim: a questionnaire for use in multinational clinical trials of patients with type 1 and 2 diabetes containing all diabetes-related QoL domains.

Item generation: Literature review, patients, items from other instruments (SF-36, the DQoL, and the HFS), and patients. 28 items drawn directly from SF-36, 59 from the DQoL, and 17 from HFS.

Items: 142 in 20 domains. The revised version contains 57 items across 8 domains.

Response format: 5-point scale.

Scoring method: Domain scores converted to 0-100.

Reliability: Cronbach’s α : moderate, good, and high for most domains (6 out of 8). Test-retest was assessed but results are unreliable due to sample and mode of administration deficiencies.

Validity and Responsiveness:

Validity: Face and content validity assessed by experts and patients. Good discriminant validity for various groups of patients assessed against demographic and clinical variables.

Responsiveness: Assessed six months from baseline showed significant changes in 4 domains related to health and treatment, indicating good responsiveness of the measure.

Burden & Acceptability

Completion time: Not reported. Time of 10’ reported for the revised version seems unrealistic.

Acceptability: Not reported.

Alternative forms: The revised version of 57 items containing only the domains of the original with high reliability and validity make it one of the most reliable and valid instruments in the field.

Cultural and Language Adaptations: German and French.

Comments:

Strengths:

- The original version captures all QoL domains related to diabetes;
- Containing entire diabetes-specific and generic measures is useful for assessing health status, QoL, and treatment satisfaction simultaneously;
- Revised version reliable and valid, but further evidence is required.

Weaknesses:

- Item generation-reduction based on trial-and-error rather than theory and empirical evidence;
- Original instrument too lengthy and unreliable; revised version still lengthy;
- Inclusion of other instruments does not improve any properties but inherits their handicaps.

Conclusion:

It cannot be considered as a diabetes-specific instrument *per se*, but as a compilation of other instruments.

8.3.2.8 “Diabetes-Specific Quality-of-Life Scale” (DSQoLS)

Background: Developed in Germany by U. Bott. First published in 1998.

Conceptual-Measurement model

Aim: to assess four components of quality of life (physical, emotional, social burdens, and daily functioning) of people with type 1 diabetes.

Item generation: Based on two existing measures, patients, health experts, and pedagogues.

Items: 39, in 6 domains: social relations, leisure time, physical complaints, worries about future, diet restrictions, and daily hassles.

Response format: 6-point scale.

Reliability: *Cronbach's α* : satisfactory to high (0.70-0.88).

Validity and Responsiveness:

Validity: Evidence for face, content, construct, discriminant, and convergent validity.

Responsiveness: Not assessed.

Burden & Acceptability

Completion time: 10-20'.

Acceptability: 96%

Alternative forms: Similar to the original, but with 5 domains (2003).

Cultural and Language Adaptations: English, but not validated.

Comments:

Strengths:

- Reliable and valid in almost all types of validity instrument.

Weaknesses:

- It concerns only type 1 diabetes patients;
- Relatively lengthy for QoL;
- Validated only in its original version (German).

Conclusion:

The English version is based on the assumption that the instrument keeps its original psychometric properties. However, these properties are not 'built-in' characteristics of an instrument, thus they "cannot be assumed to travel well" (Bradley, 1996). Thus, the instrument is unreliable for use in this study.

8.3.2.9. "Diabetes-39" (D-39)

Background: Developed in the USA by Boyer and Earp. First published in 1997.

Conceptual-Measurement model

Aim: to assess diabetes quality of life.

Item generation: literature review, and unstructured interviews with diabetes physicians, educators, pharmacists and patients.

Items: 39 in 5 domains: energy-mobility, diabetes control, anxiety-worry, social burden, sexual functioning.

Response format: 7-point Linear Analogue Scale (VAS).

Scoring method: transformation of item scores to 0-100 scale.

Reliability: *Cronbach's α :* High (0.81-0.93).

Validity and Responsiveness:

Validity: Good convergent (high correlations with SF-36) and discriminant validity (patients with known differences).

Responsiveness: Not assessed.

Burden & Acceptability:

Completion time: Not reported. Easy to complete by old and low literacy people due to the use of VAS, but high burden to administrators.

Acceptability: Low to moderate (46-73%).

Alternative forms: None.

Cultural and Language Adaptations: Danish, Finnish, Norwegian and Swedish. Also, translated, but not validated, in French, German and Italian.

Comments:

Strengths:

- High reliability in the form of internal consistency. Test-retest reliability was not assessed;
- Good validity as assessed against the SF-36 and known groups;
- Good for the patient response format (VAS).

Weaknesses:

- The item generation process and patient participation is vague;
- Low acceptability of the instrument;
- Scoring difficult for the administrator.

Conclusion:

It is not a highly used instrument, probably because of its low acceptability and high administrative burden.

8.3.2.10. “Problem Areas in Diabetes” (PAID)

Background: Developed by W. Polonsky in the USA. First published in 1995.

Conceptual-Measurement model

Aim: to tap the breadth of diabetes-related emotional distress.

Item generation: diabetes experts, and type 1 patients. No literature review, theory, or previous experience reported.

Items: single index, 20 items.

Response format: 6-point scale.

Scoring method: result converted to 1-100 scale.

Reliability: *Cronbach's α :* 0.95 – very high internal consistency. Good item-total correlation: 0.68. High test-retest reliability assessed 66 days from baseline (0.83).

Validity and Responsiveness:

Validity: Good concurrent and predictive validity, moderate to good discriminative validity.

Responsiveness: Low to moderate responsiveness assessed in 3 years period (1999-2001).

Burden & Acceptability:

Completion time: reported as 3-5'.

Acceptability: Moderate to good (70-85%).

Alternative forms: A 28-item version was announced and published, but it was never validated or used.

Cultural and Language Adaptations: translated into 12 languages, but some of them with considerable equivalence problems.

Comments:

Strengths:

- Good reliability;
- Good concurrent, predictive, and discriminative validity.

Weaknesses:

- According to its developer bad face and content validity;
- It does not cover critical areas of diabetes QoL.

Conclusion:

The instrument seems to be abandoned by its main developer, who introduced the Diabetes Distress Scale.

8.3.2.11. “Diabetes Distress Scale” (DDS)

Background: Developed in the USA by W. Polonsky. First published in 2005.

Conceptual-Measurement model

Aim: to assess the diabetes-related emotional distress for use in research and clinical practice.

Item generation: Revision of previous questionnaires, performed by health experts and patients.

Items: 17 in 4 domains (emotional burden, regimen-related distress, physician-related distress, and diabetes-related interpersonal distress).

Response format: 6-point scale.

Scoring method: summated index.

Reliability: *Cronbach's α :* High (0.93).

Validity and Responsiveness:

Validity: Limited assessment of validity against medical variables and one depression scale with inconclusive results.

Responsiveness: Not assessed.

Burden & Acceptability:

Completion time: Not reported.

Acceptability: 72%

Alternative forms: None

Cultural and Language Adaptations: None

Comments:

Strengths:

- Short instrument, addressing 4 different domains;
- Clear to respondents.

Weaknesses:

- Not properly assessed for reliability and validity;
- Addressing mainly diabetes-related distress and no other domains of diabetes-QoL.

Conclusion:

A diabetes-distress measure with inadequately proved reliability and validity.

8.4 Discussion

There are several criteria that could be taken into consideration when choosing an instrument for a particular study. A decisive factor should be the psychometric properties of the instrument. Validity, reliability and responsiveness can determine how useful an instrument is in measuring quality of life. Nevertheless Hyland argues that:

“The best way to select a QoL questionnaire is to examine the items of the scale carefully, and judge to what extent the set of items –i.e. the shopping bag of experiences- matches the requirements of the research that is to be carried out. The selection does not require a QoL expert: it can be done by anyone with a good understanding of the disease and the research requirements.” (Hyland, 2003)

The content of an instrument, or ‘*the shopping bag of experiences*’, according to Hyland, should be the first criterion for its use in a study. This content should correspond to what is considered to be the accepted definition of QoL. For this study Bowling’s (2005c) definition has been chosen and quality of life is defined:

“in terms of having a positive psychological outlook and emotional well-being, having good physical and mental health and the physical ability to do the things they want to do, having good relationships with friends and family, participating in social activities and recreation, living in a safe neighbourhood with good facilities and services, having enough money and being independent.”

However, the definition of quality of life is only one of the criteria that should be used in selecting an instrument. Bowling proposes a comprehensive list of another 23 criteria that should be considered before a decision is made (Bowling, 1995a). 17 of these criteria are considered as applicable for this research and should be taken into consideration before a decision is made. These criteria include:

- The specification of key variables;
- Decision about the use of generic and/or disease specific measures;
- Decision about the dimensions that should be included in the measurement;
- Multidimensionality of the scale to be used;
- Patient’s treatment satisfaction;
- Corroboration that the measure purports QoL;
- Patient’s participation in instruments’ development;

- Published evidence of psychometric properties;
- Scale and subscale scoring;
- Burden to administrators;
- Suitability of the measure relatively to the statistical method;
- Ethics;
- Acceptability by different strata;
- Ease of completion;
- Appropriateness of the instrument relatively to the target group;
- Patient's self reporting;
- Administration of the instrument in places the patients feel comfortable;

Furthermore, Gill and Feinstein (1994) argue that an improved quality of life instrument should include:

- The use of global ratings;
- The rate of severity and importance and
- The inclusion of supplemental items.

There are some very good instruments for measuring patients' quality of life. Garratt *et al.* (2002) undertook a systematic review to identify disease-specific measures of health related quality of life for diabetes and to examine the evidence for the reliability, validity and responsiveness of instruments. The review included instruments that were patient-assessed, disease-specific, with HRQOL as the main focus, and evaluated with adult patient populations. Out of the nine instruments they reviewed, the authors concluded that five of the diabetes-specific instruments had good evidence for reliability and internal and external construct validity: Audit of Diabetes Dependent Quality of Life (ADDQOL), Diabetes Health Profile (DHP-1/18), Diabetes Quality of Life Measure, Diabetes-39 (D-39), Diabetes Specific Quality of Life Scale (DSQOLS) and Questionnaire on Stress in Patients with Diabetes-Revised (QSD-R).

Watkins & Connell (2004) emphasised in their review of QOL measures the importance of careful consideration of the conceptual underpinnings of the available instruments, as there is little uniformity in the definition and

conceptualisation of HRQOL. However, they endorsed the use of the ADS, ADDQOL, PAID, DQOL and DSQOLS.

Fitzpatrick et al. (2006), although accepting that there was insufficient evidence to single out any particular instrument, recommend that the ADDQoL, the DHP and DQOL should attract more attention among the diabetes-specific instruments.

El Achhab et al. (2008) conclude in their review that the ADDQoL, DDS, DHP, DSQOLS, and D-39 are recommended for use, because they have good psychometric properties as well as because patients were involved in the development of these instruments. However, the assessment of validity of the DDS was not considered by its developers as sufficient.

8.4.1 The advantages of the ADDQoL

The ADDQoL incorporates some characteristics that makes it unique compared with all other instruments reviewed in this study, and in many respects a complete measure for diabetes-related QoL.

Starting from its development procedure it could be argued that it satisfies all the relevant criteria. Theory, experts and the participation of patients in the item generation phase give the instrument high content and face validity. The ADDQoL has shown evidence of good internal consistency reliability and construct validity.

Its authors claim that this measure may be more sensitive to change and more responsive to difference than earlier diabetes-specific or generic QOL measures. It is also sensitive to effects of diabetes (including treatment and complications), that cannot be captured by the measurement of treatment satisfaction alone (Bradley and Speight, 2002).

A shortcoming of the ADDQoL could be considered that its validity was measured only against the two global items of the questionnaire. No other measure was used

for testing its (criterion) validity. Thus, there is no evidence about the instruments' relationships with other quality of life measures. Nevertheless, the ADDQoL is characterised by some features that are not found in any other instrument.

First, all other instruments examine how the patient perceives the burden that diabetes has on certain aspects of life (burden-type instruments). The ADDQoL is the only instrument that examines how diabetes interferes with the patient's perception of quality of life, that is how the patient imagines his/her life without diabetes. However, seen from another perspective, the advantage of not being a burden-type instrument could also be a disadvantage. One could argue that the questionnaire demands that the patient makes value-judgements about an imagined life. This could be considered as a complex cognitive function, different from direct questions about diabetes-specific QoL.

According to some critics this complexity could be a disadvantage with this measure, as it does not allow researchers to determine accurately the impact of diabetes in the QoL domains. Polonsky (2000) pointed this out one year after the publication of the ADDQoL. In 2006 the American Food and Drug Administration (FDA) in its guidelines for patient-reported outcome measures clearly stated that it did not recommend asking patients to respond hypothetically or on the basis of a desired situation, but it would be preferable to answer on their actual condition (FDA, 2006).

The FDA recommendation was raised as a criticism of the ADDQoL by Speight *et al.* (2009), an ex-associate of the developer Bradley (Speight and Bradley 2000; Bradley and Speight 2002). The response to the FDA recommendation as well as to Speight's criticism was that although this advice is sound in some instances there are major benefits from this because a "direct question about the impact of diabetes often elicits optimistic coping responses suggesting little or no impact" (Bradley, 2006a; Brose *et al.* 2009). The issue was of great importance for the validity of the instrument, and received particular attention during the various applications of ADDQoL. The issue is discussed in the ADDQoL-Gr validation section of this thesis (Chapter 8).

Another characteristic of the ADDQoL is that it allows answers that indicate positive effects on certain domains. The usefulness of this characteristic was doubted during the translation process, as it was difficult to accept that a disease like diabetes might have positive effects on QoL. In a private communication Professor Bradley was asked about the value of the positive effect answers and whether this intriguing characteristic should be omitted. Professor Bradley answered that the positive effects of diabetes should not be expected to be of the same importance as the negative ones, but in some cases such as family relationships or dependence on others a positive response could not be *a priori* rejected. The developers of the ADDQoL recognising the fact that there are only a few positive responses to diabetes had already reduced the positive responses from three, in the initial instrument, to one in the 19 item version. With the benefit of hindsight the view of Professor Bradley was proved correct. Four patients participating in this study reported a positive impact on their lives from diabetes.

A third interesting feature of the ADDQoL is that it contains two overview-global items: one of a generic nature concerning quality of life in general, and a disease-specific one, relating QoL with diabetes. The advantages of using global questions alongside with a multi-item questionnaire have been discussed in Chapter 4.

A fourth unique aspect of ADDQoL was that it asks the respondents not only to state how different each domain of life would be without diabetes, but also to rate the importance of this particular domain for their QoL. In this respect the ADDQoL satisfies the other recommendation made by Gill and Feinstein (1994), who suggest that:

“... patients should be invited to rate not only the severity or magnitude of problems in those domains, but also the importance of the problems”.

This was a breakthrough for QoL questionnaires and the ADDQoL is reported as the only instrument at the time that used an importance weighting for each item. As Fitzpatrick (1999) commented by the time the ADDQoL was published:

“The vast majority of instruments fail to address the diversity of priorities and concerns of respondents and the varying weights and values which they attach to their concerns”.

This characteristic of the ADDQoL might be the answer to a basic problem of this research, namely the differences in emphasis and priorities that exist among people with different socioeconomic, cultural and demographic backgrounds. The ADDQoL, by allowing the respondents to grade the importance of each aspect of life, provides the capability to detect value differences among different strata of society, a feature considered by Bowling as necessary for QoL measures (Bowling, 2005a).

Another unique feature of the ADDQoL is the fact that allows the respondents to answer only the questions that are relevant to them. At first glance one could say that this degree of freedom could probably add to the content validity or even the acceptability of the instrument. However, this is something a lot more than an attempt to improve the acceptability of the questionnaire. By answering questions relevant to only him/her, the patient gives his/her own quality of life domains. Standardised measures have the same predetermined questions and answers for all respondents. Thus, they try to measure a QoL concept that might be irrelevant to the individual patient.

However, by asking the patient to rate the importance that certain domains have for his/her life, results in a personalised definition of QoL. This could probably be part of the answer to the fundamental problem of QoL measures (i.e. the definition of QoL). In this respect, the ADDQoL comes close to the view, expressed by Calman, that quality of life:

“can only be described and measured in individual terms, and depends on present lifestyle, past experience, hopes for the future, dreams and ambitions” (Calman, 1984).

Later, Gill and Feinstein (1994) on the same line argued that:

“... QoL is something perceived by each patient individually. The need to incorporate patients’ values and preferences is what distinguishes quality of life from all other measures of health”.

And they continued concluding that:

“...because QoL is a uniquely personal conception, denoting the way that individual patients feel about their health status and/or nonmedical aspects of their lives, most measurements of QoL in the medical literature seem to aim at the wrong target. QoL can be suitably measured only by determining the preferences of patients and supplementing (or replacing) the authoritative opinions contained in statistically ‘approved’ instruments” (ibid).

The ADDQoL seems to espouse better than any other instrument the view expressed above.

The open question is another unique aspect of the ADDQoL. Once again the authors seem to follow the Gill and Feinstein recommendations, who argue that:

“An instrument that contains standard items should be augmented with supplemental items that patients can add to denote important factors that may not have been included in the instrument” (ibid).

Nevertheless, the authors do not seem to have made their minds up about how they should exploit the data that might be collected by this question.

Finally, another advantage of the ADDQoL is that its relatively short length makes it easy to be used either on its own or simultaneously with a health status instrument, such as the SF-36.

8.5 Conclusion

Taking into consideration all the above criteria I decided that the ADDQoL should be the instrument of choice as the diabetes-specific measure of this study.

In brief, the advantages of the ADDQoL compared with the other existing instruments are:

- It comes close to the accepted definition of QoL (Bowling 2005c). It contains items covering psychological and emotional issues, physical ability, relationships with family and friends, independence, financial status, activities and recreation;

- It comes closer than any other instrument to the view that QoL can be described and measured in individual terms. It allows the respondent to answer only the questions that are applicable to him, and constitute his/her definition of QoL. The definition of QoL used for the measure's development was, according to its developer (Bradley, 2006), the definition proposed by Joyce '*QoL is what the individual says it is*';
- Its items cover the three areas that the WHO QoL Group considers as dimensions of quality of life, that is physical, psychological and social functioning;
- It rates not only the severity but also the importance of the items concerning the QoL;
- It contains two global items that can be used as dependent variables for overall QoL;
- It allows the respondent to add any complementary item;
- It is shorter than most other instruments (with the exception of the ADS and DDS);
- It satisfies all criteria for the item generation process;
- There is enough evidence on its psychometric properties;
- It is the most widely translated instrument, allowing international comparisons.

All the above advantages, combined with the understanding of the disease gained after years of experience with diabetes patients, and knowing the research requirements make the choice of the ADDQoL the best solution for this project.

PART III: Producing the ADDQoL-Gr

Chapter 9: Translation and cultural adaptation of the ADDQoL

9.1 Introduction

“Language is the software of a civilisation”

Helen Glycatzi-Arveler- Greek historian

Language, according to the Oxford English Dictionary, is the whole body of words and of methods of combination of words used by a nation, people, or race. Language is an acquired feature and not an instinctive or inborn characteristic. It is a major component of culture that defines and at the same time is defined by the society that uses it. As such language is a ‘carrier’ of culture and not a culturally ‘immunised’ concept. Consequently, the translation of a measure is not an “etic account” that is, it is not a culturally neutral issue. The whole process should be considered as an “emic” issue, an issue affected by culture. Translation and equivalence are therefore inextricable concepts and the second should be considered as a prerequisite for establishing that a translated measure is reliable and valid.

Cultural adaptation of an instrument, according to the MAPI Institute (an international non-profit organisation specialising in Health Related Quality of Life research), is the passage from one language to another with cross-cultural equivalence in appropriate, acceptable and natural language. The problems that cultural equivalence present to a translation process are many and of various magnitude and importance.

9.2 Cultural equivalence

“Culture is what is left after everything we have learned has been forgotten”

Garfield Bromley Oxnam (1892-1963)

The problem of cultural equivalence can be present in a variety of forms and may concern different aspects of life or dimensions of quality of life. In some cases people are unwilling to answer questions which are considered embarrassing and

cause distress (Fayers *et al.*, 1998). Sex life for example is a very difficult question in many Asian societies and for women in the Muslim populations worldwide. In a study which took place in Singapore almost half of the respondents refused to answer the question about sexual satisfaction (Cheung and Thumboo, 2006).

Hiding of disease because of the ‘stigma’ attached to it is another possibility among people with chronic disease in many cultures. Differences also exist in the semantic equivalence of some items with idiomatic expressions which usually refer to situations. The meaning of colours, for example, is different among cultures (Streiner and Norman, 2008; Breugelmans, 2009).

Writers have not reached consensus on terms and methods of translating QoL measures but the equivalence aspect is central to all translation methodologies. As a concept however it has not been described adequately enough. Herdman *et al.* (1997), reviewing the literature concerning generic HRQoL instruments, found references to 19 different types of equivalence with substantial variation of definitions and varying degrees of precision. They argued that seven types of equivalence were the most frequently used: conceptual equivalence, semantic equivalence, functional equivalence, scalar/metric equivalence, scale equivalence, technical equivalence, and operational equivalence. They also found that four types of equivalence (criterion, content, item, experiential) were less frequently used.

In a subsequent article Herdman *et al.* (1998) argued that six types of equivalence Conceptual, item, semantic, operational, measurement, and functional equivalence are sufficient for examining not only how to achieve equivalence but also whether adaptation should take place.

Stewart and Napoles-Springer (2000) in a literature review of translation methods provided taxonomy for assessing equivalence with six different types. Five of them were the same as Herdman’s *et al.* (1997) taxonomy, with criterion equivalence having replaced the functional one.

Five types of equivalence (conceptual, item, semantic, psychometric, and operational) were examined for the development of the ADDQoL-Gr.

Conceptual equivalence is the first and most important type of equivalence because it refers to the need of determining: “*what it is that is to be measured*” (Bowling 1995b). It is a hard to define type, as there is considerable lack of consensus among writers. Herdman *et al.* 1998 provide a list of 20 definitions with substantial differences among them. In general terms conceptual equivalence exists when: the concept *per se* exists in the target culture; it is relevant and acceptable in both cultures; items have similar meaning; and the value or emphasis placed on different domains is similar (Stewart and Napoles-Springer, 2000).

A typical example representing the problem of conceptual equivalence is the health-related quality of life concept in countries like Japan or Korea, where there is no equivalent of the term. Health related quality of life in Japan is discussed in terms of “patients’ harmony”. However, there is no western measure capturing the concept of harmony (Choe *et al.* 2001). Thus, conceptual equivalence in these countries might be achieved only by what Choe describes, citing Higuchi, as “*the patient’s harmony with the world, with others, with himself and with death*” (*ibid*), rather than HRQoL as conceptualised by western writers.

Conceptual equivalence can be investigated by reviewing literature concerning health and health-related quality of life, examining questionnaires dealing with similar topics in the target language, and conducting health experts in the target culture. These should however be considered preliminary work for examining conceptual equivalence. The main body of work and the only way of establishing that conceptual equivalence between the two versions exists is the empirical exploration of the concept in the target language and its comparison with the source.

Item equivalence exists when the items composing the questionnaire are identical, equally relevant, important, and acceptable in both cultures (Herdman *et al.* 1998; Stewart and Napoles-Springer, 2000). Item importance concerns both the question of values as well as of priorities of the respondent (see Chapter 4). These values and priorities have to be reflected in the target version, thus item equivalence is prerequisite for a culturally adapted questionnaire. Bowden and Fox-Rushby (2003)

however, in reviewing the process of translation and adaptation of generic HRQoL measures, stated that the majority of writers fail to report partially or extensively on item equivalence.

Item equivalence may be investigated first by a qualitative examination of the relevance of items followed by an assessment of the psychometric properties. Herdman *et al.* (1998) propose that qualitative examination should be approached by methods using expert judgement, such as the Delphi technique, or more appropriately by consulting members of the target group. For quantitative assessment they propose that Rasch item analysis may be useful and internal consistency should be examined by using Cronbach's α in order to estimate the extent to which items are measuring the same underlying construct.

Semantic equivalence refers to the transfer of meaning across different languages. It is obtained when questions mean the same thing and create similar effects to respondents in different languages (Herdman *et al.* 1998; Stewart and Napoles-Springer, 2000). Forward – back translation, expert reviews, as well as cognitive debriefing interviews are some of the methods widely used to achieve and assess this type of equivalence

Psychometric equivalence aims to ensure that comparable psychometric properties, mainly in terms of reliability and validity, are observed between the two languages versions. The methods for assessing measurement equivalence are the same as the ones used for measuring the psychometric properties of HRQoL measures in general (see Chapter 5). However, these assessment methods cause some confusion between item and measurement equivalence. Bowden and Fox-Rushby pointed out (2003) that the same methods (e.g. Cronbach's α and Rasch analysis) are proposed for measuring both types of equivalence. Thus, the information gathered during the assessments is used to interpret item as well as measurement equivalence, making the distinction between those two types difficult.

Operational equivalence exists when the method of administration, questionnaire format, item format, instructions, and measurement methods between the two

versions are similar. It has been proved that the administration mode of a questionnaire, the coding, or even the question order and the response-choice available to respondents are parameters that can influence the responses and thus the results. (Bowling, 1995b; Bowling, 2001; Bowling and Windsor, 2008). This is equally true for instruments that have been translated into another language. Methods for investigating operational equivalence include literature reviews of similar instrument use in the target culture, sociological data on cultural norms, expert panels, pre-testing, cognitive debriefing and comparison of results with the source version.

9.3 Method

Another area where there is little consensus is the methodology and/or terminology for translating an existing QoL measure into another language and culture. Guillemin *et al.* (1993) call the process ‘cross-cultural adaptation’ of the HRQoL measure, which has two components, the translation of individual words and sentences from one language into another and secondly the adaptation of idioms, cultural context, and lifestyle.

The MAPI Research Institute uses the term ‘cultural adaptation’ which consists of two phases, linguistic validation and psychometric validation. The methodology is similar to the one proposed by Beaton *et al.* (2000) with one more phase - that of international harmonisation. The process of cultural adaptation, according to MAPI, aims to ensure that the new version is:

- Conceptually equivalent to the original instrument;
- Culturally relevant and acceptable to the target population;
- Psychometrically comparable.

Acquadro *et al.* (2008) published a literature review, in which they investigated the existing methodologies for HRQoL questionnaire translations. They concluded that each method proposes a different sequence of translation events and weights each of those steps differently. They then proposed a multistep methodology which

contains 11 steps for translating an instrument into another language. The first step concerns the information needed for potential contacts with the developers of the HRQoL questionnaire, as well as their awareness about the intended translation and/or their participation to the project. The next 4 items (2-6) concern the forward translation process; items 6-8 deal with back-translation; item 9 deals with the approval of the forward translation in case there is no back-translation; item 10 concerns the pilot testing of the target version with people from the target population. Finally they propose International Harmonization (item 11) as used by the MAPI Research Institute.

The initial step prior to translation was to communicate with Professor Bradley, the developer of the ADDQoL and ask for permission to translate the measure into Greek. The terms and conditions of translation are outlined in the agreement between the Royal Holloway and Bedford New College, the developer of the ADDQoL Prof. C. Bradley, Prof. A. Bowling and the author of this study T. Pisimisis (Appendix D).

The translation and cultural adaptation of the ADDQoL into Greek was performed according to the MAPI Research Institute's methodology and the process prescribed by the developer of the ADDQoL (Bradley, 1994; 2007). Guidance was also provided by Prof. Bradley's team throughout the translation. Each of the nine phases of the procedure, as it is described in the agreement, was reported in detail to the developer through ten reports. The nine phases are:

- Forward translation;
- Back Translation;
- Revisions to Forward Translation;
- Review by psychologist and clinician;
- Interviews with patients (called cognitive debriefing in the agreement);
- Review by author;
- Production of final version of the questionnaire;
- Proofreading;
- International Harmonization.

The submission of the ten reports requested by the developer has been a contractual obligation for me and included the following:

- Linguistic Validation Plan, which included names and details of the persons that would be involved in the process. This report was submitted during the preliminary phase before the contract was signed.
- Copies of the working translations, which included three forward translations and two back translations. They consist of a series of interim communications between the author of this thesis and the linguistic expert of Prof. Bradley's team Mrs R. Plowright.
- Forward Translation report with all discussions that took place between the author of this work and the developer's team. This report was my final proposal to the developer for the Greek version of the ADDQoL.
- Back Translation report including the discussions.
- Clinician review report.
- Psychologist review report.
- Interviews with patients report (called by its author: Cognitive Debriefing Report).
- Proof Reading Report.
- Electronic copy of the final version of the questionnaire.
- International Harmonisation report.

Details about the aim of each phase are given below (sections 9.3.1 -9.3.7), where each phase is discussed. The aim of each stage, the methods used, as well as the reports required by the developer are given in Appendix D, where the Linguistic Validation Process is fully described. Communication with the developer's team was continuous and when the solutions proposed by me were accepted a report was prepared and sent to Prof. Bradley containing my final proposal. Details about the content of the reports are given in the following sections. The problems faced during the entire Linguistic Validation Process, the solutions given, and the final outcome of the translation and cultural adaptation are described in the results section of this chapter (9.4.1), where the equivalence of the two instruments is discussed in detail.

Details about the aim of each phase are given below (sections 9.3.1 -9.3.7), where each phase is discussed. The aim of each stage, the methods used, as well as the reports required by the developer are given in Appendix L, where the Linguistic Validation Process is fully described. Communication with the developer's team was continuous and when the solutions proposed by me were accepted a report was prepared and sent to Prof. Bradley containing my final proposal. Details about the content of the reports are given in the following sections. The problems faced during the entire Linguistic Validation Process, the solutions given, and the final outcome of the translation and cultural adaptation are described in the results section of this chapter (9.4.1), where the equivalence of the two instruments is discussed in detail.

9.3.1 Forward Translation

The main aim of the forward translation was to establish that there is equivalence of the concepts that the ADDQoL purports to measure (i.e. general health and quality of life). Also the original questionnaire was examined to establish that there were no items with idiomatic expressions similar to the ones described in the literature (Guillemin *et al.* 1993; Choe *et al.* 2001; Breugelmans, 2009).

The first task of the translation process was to clarify the content of the questionnaire, by clarifying and defining the concept that each item investigates. This was necessary in order to ensure that each item is correctly reflected in Greek. Three parallel forward translations were carried out by three translators, native speakers of Greek, fluent in English and permanent residents of Greece (Guillemin *et al.* 1993). One of the translators was the author of this study. All three translators worked independently from each other.

A review of discrepancies among the three translations and reconciliation was carried out by a fourth person, who is again a native speaker of Greek and fluent in English. In the reconciliation meetings the three translators and the reconciliator produced an intermediate forward translation. A report was prepared by the author

of this study which was forwarded to Professor Bradley's team. This report included the forward translation as well as all difficulties and problems encountered, the decisions made and the reasons behind them. It also included some suggestions for changes in the format of the questionnaire which have been rejected for reasons of harmonisation with other versions of the ADDQoL. Consecutive discussions followed, a 29 pages report was produced and agreed by both parts, and a final forward translation was submitted for back translation.

9.3.2 Back Translation

Back translation is a process in which the target-language translation of a measure is translated back by other translators into the original language. It aims to ensure the equivalent meaning of items in both languages. Back translation is the most commonly used procedure to verify, assess, and control the quality of a translation. Thus, the forward translation was sent for back translation to two bilingual translators whose native language is English. Both backward translators worked independently and were completely "blind" to the original ADDQoL. The first translator was employed by Professor Bradley, the second one by the author of this study. The first back translator remains unknown to the translating team. The second back translator Shona Carter is a qualified psychologist and experienced with psychological questionnaires.

The result of both back translations revealed no substantial differences with the original. The subtle differences that occurred had been predicted prior to back translation. Minor modifications of the forward translation draft were made to eliminate discrepancies between the original and the two back translation versions. The 'revision to forward translation' phase was completed without having to return to the back translators as the two translations were almost identical. A back translation report was prepared by the author of this study and submitted for review to the owner of the measure. Further discussions and modifications were carried out before the final version was sent to be reviewed by health professionals, according to the guidelines provided by Professor Bradley and the signed agreement for the

translation of the ADDQoL. Retranslation of any item was deemed unnecessary as the submitted version was accepted by the developer's team.

9.3.3 Review by health professionals and patients

This phase of cultural adaptation examines the degree of agreement between the phrases used in the translated questionnaire and those used by health experts and patients, relating to the nature of the disease, its treatment, or associated symptoms. The translated questionnaire was sent to a diabetologist and a health psychologist working for a diabetes centre in Athens. M. Benroubi is a diabetologist, fluent in English, with a doctoral degree in medicine from King's College London. She is director of the Polycliniki Diabetes Centre in Athens and ex-president of the Hellenic Diabetes Association. K. Vareli, also bilingual, is a health psychologist who has been working with diabetes patients for the last 25 years. The two health professionals worked independently, and upon completion of the review a meeting took place to discuss any suggestions.

With this review the first five stages of the contractual obligations of the translator to the owner of the ADDQoL had been fulfilled. However, various writers have pointed out that usually translators, back translators, and reviewers have a much higher level of education and reading comprehension than the average respondent. Also, their living experience in the country of the original language of the instrument provides advantages in understanding the intentions of the original meanings (Mallinckrodt and Wang, 2004). To ensure that no such problem is hidden in the translation five patients were asked to answer the questionnaire and give their opinion about the wording of the questionnaire. This step was not part of the agreed process and it was taken as an additional precaution. The results were satisfactory and then the "health professional's review report" was sent to Professor Bradley's team. The report was reviewed by the author of the questionnaire and their consent to continue with the Cognitive Debriefing was given.

9.3.4. Cognitive Debriefing

This phase of development of a questionnaire is used to establish that whether concepts and items are understood by respondents in the same way that the instrument developer intends. It involves follow-up questions in order to gain a better understanding of patients' interpretation of the items (FDA 2006).

According to the MAPI Institute cognitive debriefing in cultural adaptation aims to assess the clarity, intelligibility, appropriateness, and cultural relevance of the translated version to the target population. It is a means to ensure that conceptual equivalence between the two versions is retained and might be considered as a way of 'bridging' between languages and cultures (Acquadro *et al.* 2008: 518).

Five interviews were conducted during the first week of April 2009 by the author of this study. Table 2.1 shows the characteristics of the people recruited for the interviews.

Table 5: Characteristics of the people recruited for the cognitive debriefing

Patient	Compl time	Age	Sex	Type of D	Marital status	Age leaving educat	Job / profession	Treatment	Durat ion	Treatm Duration
R 1	56'	52	M	2	M	23	businessman	insulin	17	4
R 2	44'	49	F	1	M	20	private employee	insulin	32	32
R 3	52'	51	F	2	M	18	Post-Office employee	insulin	27	10
R 4	41'	65	M	2	M	12	retired builder	tablets	15	14
R 5	45'	45	F	1	M	15	school-bus driver	insulin	33	33
Mean	47.6	52.4								
Median	45	51								

The interviews were taped and a report including interview transcriptions was sent to the developer of the ADDQoL. The first observation was that all respondents, with different background, education, age, and duration of diabetes faced largely the same difficulties in interpreting the questions, and had similar views on alternatives presented to them. Another result was that the respondents faced more

problems related to the operational equivalence than to the semantic one, which was the main problem for the author of this study and the translating team in general.

9.3.5 Review by author and production of final version

This was the stage where the developer examines the proposed final version of the translated questionnaire. A report was sent together with the completed template of the ADDQoL-Gr to Professor Bradley and her team. The original format was largely kept, as well as font, font size, page structure etc. The original template was used without adding any extra header. A slight problem emerged with respect to the copyright statement of the final version of the ADDQoL-Gr, but it was soon resolved and the final version was agreed.

9.3.6 Proofreading

The aim of proofreading is to establish that the final version is fully understood by people who did not participate in the translation process. The ADDQoL-Gr. was proofread by two individuals, native Greek speakers and a member of Professor Bradley's team. This person should be familiar with the questionnaire but not engaged in the translation process, whose task was to examine formatting issues, using the original English format as a template. Two suggestions concerning the vertical spacing of a line and the omission of two full stops at the end of sentences were made at this stage. The final version of the ADDQoL-Greek for Greece 19.2.09 (from Standard UK English rev. 1.4.06) may be found in Appendix B of this thesis.

9.3.7 International Harmonisation

International Harmonisation (IH) is a stage performed mainly by the MAPI Institute. It aims to ensure comparability between the original and target versions

as well as to perform a further quality control (Acquadro *et al.* 2008). IH is the only phase of the cultural adaptation that takes place in one country, where the coordinating centre (i.e. MAPI Research Institute) and the developers and translators of the various languages meet. The purpose of the meeting is to achieve ‘harmonisation’, not in the sense of compromising differences, but to establish that the major types of equivalence exist among the versions (*ibid*). IH does not have the same importance for all languages. Greek for example is used by a homogeneous population and so does not have to be harmonised to the same extent as Spanish which has 14 different versions of the same questionnaire (Juniper, 2009). A meeting that took place in Lyon – France in October 2009 accepted the ADDQoL-Gr as equivalent to the other versions of the instrument.

9.4 Results

9.4.1 Equivalence of the ADDQoL-Gr.

Cultural problems (e.g. concerning conceptual equivalence) did not emerge during this work. All respondents freely discussed their quality of life, as well as problems with their diabetes, sex life, worries etc. The absence of cultural problems also indicates that the author of the ADDQoL has avoided any idiomatic expression that might create semantic differences between the two versions.

The paragraphs below might be considered as a summary of a series of communication between me and the developer’s linguistic expert concerning semantic, conceptual or operational problems discussed during the entire process. It is also a summary of the reports that have been sent to Prof. Bradley’s team as an end-result of this communication.

9.4.1.1 Conceptual equivalence

No problem was identified with conceptual equivalence of the two versions. The concept of Quality of Life was well perceived by patients and initial doubts that it

could be confused with ‘standard of living’ or ‘lifestyle’ were not confirmed. The respondent’s perceptions of the QoL concept were nearer to the widely accepted views, compared with those of the physicians approached throughout the translation process. Before the patients were asked to answer the global question about their QoL they were asked to describe how they perceived the concept *per se*. The answers were taped for further qualitative assessment. The answers given during the interviews were issues like ‘health’, ‘family life’ ‘peaceful family life’, ‘social relationships with people next to us’, ‘good time’ ‘entertainment’, ‘journeys’, ‘peace of mind’.

On the other hand, physicians both in private conversations and in public speech equate quality of life with ‘perfect’ glycaemic control and intensive treatment. They consider control as the only way to avoid complications, and so achieving a good QoL. This iatrogenic approach may be observed in various parts of the world, but it is not as evident in literature as it was in discussions with diabetologists in Greece. They were not only unaware of the developments in the QoL field during the last two decades, but also of the very existence of the concept *per se*. The enormous discrepancy between the two groups (patients – physicians) might be an issue for further research in Greece.

9.4.1.2 Semantic equivalence

There were some considerable problems in this field. The problems described in this section appeared during various phases of the procedure and the solutions emerged after discussions between me and the developer’s team, health experts and patients. In the end, and after trying different words or expressions the decisions taken were tested and proved correct in the patient interviews process (Cognitive Debriefing phase). The problems may be summarised as follows:

- Instructions between overview item I and II: *“Now we would like to know how your quality of life is affected by your diabetes, its management (including medication, visits to the doctor, and food) and any complications you may have”*. There were doubts about the translation of the words

‘management’, ‘medication’ and ‘food’. There were fears that the word management in Greek might refer to administration, which has no relevance to diabetes-management. The equivalent word for medication was feared that might be too scientific for low literacy level respondents. After discussion with the psychologist, physicians, and patients the Greek equivalent of ‘management’ was used without any problem.

- The word ‘statements’ on page 2 of the instructions was translated to ‘questions’. The reason for this change was that ‘statement’ in Greek implies something very official and solemn. Thus, the word ‘questions’ was used, which is easily understood because it is contained in the word ‘questionnaire’.
- Item 3: ‘local or long distance journeys’. In Greek different words are used for local and long journeys. A “journey” always implies long distance. The solution given was to add a word similar to the English word ‘movement’ next to the word ‘local’. Thus the item was translated to ‘local movements and long journeys’. Professor Bradley’s team informed the translator that this problem was faced in other languages (e.g. French) and after consulting the back translator they accepted the addition of the word ‘movement’.
- Item 10: The word ‘physical’ from the phrase ‘physical appearance’ was removed because ‘appearance’ in Greek implies the word ‘physical’, and so without removal would be a pleonasm.
- Item 12: The phrase ‘my motivation would be’ was the most difficult problem as far as semantic equivalence was concerned. According to Guyatt (1993: 461) there are words that do not translate well and faithfulness to the original represents a procrustean approach in the sense that translators find the closest meaning, which is not well-suited. The only word in the ADDQoL that falls into this category is the word ‘motivation’. This word in Greek is related and would be perceived by lay people as ‘incentive’ for something specific (e.g. productivity or earning money). Initially, the word ‘diathesi’ was added to the word ‘for life’. Translated into English this would mean ‘mood for life’ or ‘a positive frame of mind for life’. The word ‘life’ in Greek, further to its biological dimension, covers the notions of

‘determination/energy/willingness to do things’. After discussion with both lay people and diabetes patients, it was decided to add the word ‘life’ and keep the word ‘motivation’, which implies a dynamic condition, while the word ‘diathesi’ (mood) relates to a more static situation. The developers of the ADDQoL found item 12 “an interesting conundrum” and they kept it as an option for future translations.

- Item 13: The problem with the statement “...*the way people in general react to me would be*” was with the word ‘react’. The verb was considered ‘strong’ as it implies some sort of ‘counter-action’ or ‘confrontation’ and not just ‘behaviour’. The developers were asked if the use of the word was intentional and questioned why verbs like ‘behave’ or ‘respond’ were not used instead. The word *react* was however intentional; it encompasses the reaction of people to the ‘difference’ of people with diabetes (blood-glucose measuring and/or insulin injections in public, fear of hypoglycaemia). However, they stated that this item might be considered for removal in a future shorter version of the ADDQoL, but for current purposes has to be kept as close as possible to ‘react’ and the Greek equivalent of the verb react was used.
- Item 17: “... *I would have to depend on others when I do not want to*”. Two problems occurred with the translation of this item, one concerning semantic the other operational equivalence. The first one was the verb ‘depend’ followed by the phrase ‘when I do not want to’. It was thought that the phrase carries a negative emotional connotation and that no one wants to depend on others at any time. However, the statement implies that there are cases that dependence might be wanted by patients, something that created some doubts to the author of this study about the value of such a perception. The doubts were based initially on personal value judgements and later, substantiated by literature, that considers autonomy to be one of the three innate, essential and universal psychological needs (the other two being competence and relatedness) (Ryan and Deci, 2000). Furthermore autonomy is considered as a: “*basic human need and a universal precondition for any individual action in any culture*” (Devine *et al.* 2008). As such there should not be any question that might elicit answers implying

that autonomy is a matter of controversy. Professor Bradley was asked whether the phrase “when.....” could be removed, considering that the statement refers to an unrealistic and hypothetical situation and moreover could create some degree of confusion. The answer was that the verb ‘depend’ was used intentionally and in practice it has been established that sometimes people with diabetes choose to depend on others and enjoy this kind of dependence, although objectively they can have a high degree of self-efficacy in managing diabetes. They also noted that initially dependence is considered as an unwanted situation “*till you start asking people and then it turns out to be less absolute*”. With the benefit of hindsight and after listening to many people with diabetes, it was realised that there are people who enjoy depending on others. In a three-day conference of the Greek Federation of People with Diabetes that took place in Salonica (October 2009) one of the speakers characterised diabetes as her “best friend” because it was: “*the cause for all the love, care, and protection she received in her life*”. Finding this statement provocative the author of this study asked the patient to explain her statement and she replied that she was happy to be dependent for “quite a few things”, while she wanted to do other things on her own. The things she enjoyed to be ‘dependent’ concerned mainly diet, treatment, family relations, and social relations. She considered that dependence-due-to-diabetes was the cause for better treatment and warmer relations. An answer to this problem could probably be found by taking into consideration that there is a difference between the concepts of independence and autonomy. Independence means not relying on others while autonomy means acting with the experience of choice. Thus, one could be autonomous and at the same time rely on others rather than act independently (Deci and Ryan, 2008). The final answer to this problem will be given by the results of this research, which will show whether the independence question is bipolar.

- Item 19: “*...my freedom to drink as I wish (e.g. fruit juice, alcohol, sweetened hot and cold drinks) would be*”. The translation of the word ‘sweetened’ in Greek refers to the word ‘sweetener’, which again refers to chemical substances like ‘aspartame’. It was considered that there is a

semantic difference between the two words and it was decided to use the equivalent of the English word ‘sugared’, which translates best the statement.

9.4.1.3 Operational equivalence

Four problems occurred during the translation process concerning operational equivalence and some changes to the original formatting and wording of the statements was necessary before the questionnaire was tested. The first two changes attracted considerable attention because they were affecting the structure of the questionnaire, something that could create problems with International Harmonisation. The changes were considered necessary by the researcher however to achieve operational equivalence and reliability required for the questionnaire.

The first problem that arose during the preliminary discussions with patients was confirmed during the interviews with the patients. It related to the instructions of the introductory question of items 2, 4, 6, 8, and 9. The responses to these questions are:

Yes ☐ If *yes*, complete (a) and (b).

No ☐ If *no*, go straight to 3a.

For reasons that have not been fully understood almost all the respondents were confused with the repetition of the words Yes and No on the same line. When the instructions were explained to them they seemed to be unhappy with the explanation and in some way embarrassed. The issue was discussed with Professor Bradley and her team and after proposing to them various alternatives it was decided that the responses should be changed to:

Yes ☐ No ☐

If *yes*, complete (a) and (b). If *no*, go straight to 3a.

The change was proved to be successful during the interviews when both versions were tried. The issue was discussed with the developers for further examination of the original version.

The second major problem that arose during the preliminary discussions was that when the patients answered the (b) section of the item (i.e. the importance of the item in their life), they did not answer regarding the importance but in relation to the concept itself. For example the answer to the statement '*my financial situation is: very important, important etc.*' the answers received referred to a bad or good financial situation. Similar answers were elicited with living conditions and sex life. This could be proved a serious problem for the administration of the questionnaire and the author of this study proposed that the structure of the whole statement should change by adding the words '*for me*' at the beginning and the word '*something*' at the end. Thus, the statement would be '*for me, my financial situation is something:*'. The issue was discussed with the psychologist and the diabetologist and after their agreement it was proposed to the developer of the questionnaire. Although it was a major change to the questionnaire's structure it was considered reasonable and the final decision was taken after the patient interviews where both versions were tested and the second version was adopted.

The third operational problem that had to be resolved concerned the translation of p.1 instruction 4. The instruction states: "*Now we would like to know how your quality of life is affected by your diabetes, its management (including medication, visits to the doctor, and food) and any complications you may have*". The words in brackets had to be translated and included as an alternative in the CDs, but their inclusion in the final version was not necessary. This was an option given by the developer in order to facilitate the perception of the word 'management' in case the Greek equivalent did not have a sufficiently broad meaning to cover all three aspects of management. The health experts used for the translation as well as the patients consulted confirmed that the equivalent of 'management' was used in diabetes jargon and therefore use of the word should not be problematic. The patient interviews proved that 'management' was well perceived by the respondents and it was decided not to include the phrase in brackets in the Greek questionnaire.

Item 17 presented another operational difficulty. The statement is "*If I did not have diabetes, I would have to depend on others when I do not want to*". The phrase was considered as complicated and to some extent confusing because it contains two

negations at the same sentence ('did not' and 'do not'). Although it is not a syntax error, this kind of expression is not very acceptable in written Greek and can only be found in an extempore speech. The problem was presented to the developers and with their agreement the second 'not' was replaced by a phrase similar to 'despite my will' or 'unwillingly', which was considered as operationally more correct. The phrase worked well during the interviews.

9.4.1.4 Item and psychometric equivalence

The qualitative aspect of each item was examined during discussions with health experts and patients. The final estimation for these two types of equivalence cannot be assessed unless the new instrument is field-tested for its psychometric properties. Thus, a cross-sectional survey was conducted and the results for the psychometric properties of the ADDQoL-Gr and its equivalence with the original are discussed in chapter 10.

PART IV: Survey of the Greek Population

Chapter 10: A Cross Sectional Survey of the Diabetes Population in Greece

10.1 Introduction

Initially the survey will enable investigation of the reliability and validity of the ADDQoL-Gr and when its psychometric properties are established it will examine the association that medical and demographic variables have on quality of life (QoL) and health status (HS) of Greek people with diabetes.

Due to their association with QoL these variables are usually called by investigators predictors or determinants (Rubin and Peyrot, 1999). The terms will be used in this research only to describe the relationship between each of the two outcomes that is QoL and HS with the demographic and diabetes-related variables. As mentioned in chapter 5 the direction of causality between all those variables is complex and sometimes reciprocal. However, this problem will not affect the results of the study, as QoL and HS are considered *a priori* as outcomes.

A generic measure, the SF-36, will be used as criterion for the ADDQoL-Gr validation as well as for the HS assessment. The reasons for choosing the SF-36 are given in section 10.2.2.3.

10.2 Method

10.2.1 The sample

A principal concern was to recruit a sample as representative as possible. Ideally, the analytical sample would be as representative as possible of the entire Greek diabetes population. To this end, a probability sampling technique either in the form of simple or systematic random sampling would be the best way of conducting the survey.

Nevertheless, certain problems emerged concerning the availability of diabetes patients for conducting this research. The number of people with diabetes in Greece is not known, because there is no diabetes registry in the country. Patients visit any clinic at their own free will, without any referral system. The choice is made by them and depends mainly on the reputation of the hospital or their loyalty to the diabetes-professionals of the clinic. Even in the case that some clinics would keep some kind of records, the directors of the diabetes centre, who kindly have given me permission to conduct the survey in their establishments, would never give lists with patients, especially without their prior consent, because this is prohibited by law. Therefore, the sample is not representative of the entire diabetes-population of Greece.

However, bearing in mind the limitations of the sampling technique, this was the first attempt of collecting data at a large scale in eight different sites for validation of the Greek the diabetes-related quality of life instrument. Also, pragmatically this was the only way to get access to patients and conduct the survey.

There are 131 secondary care or teaching hospitals, 12 social security and independent hospitals and around 50 hospitals in the private sector (Figure 1). Most of them do not deal with diabetes on an outpatient basis. Approximately 65 of them have a diabetes clinic that usually works on a part time basis. Even this number is not certain because the function of the diabetes clinic depends mainly on the presence of a diabetologist, which is not on a permanent basis (mobility etc.). Having discussed the limitations occurring from the type the sample this should include patients from medical centres in various parts of the country, from a range of settings, with various socioeconomic backgrounds.

Special care was taken for the testing site selection process. The first concern was to select the most representative diabetes centres using hospital size, type of hospital (secondary or tertiary), as well as their reputation as selection criteria. The second concern was to avoid duplication of the types of institutions. Recruiting a sample from two or three teaching hospitals would have been a relatively easy task. However, although teaching hospitals accept patients from different parts of the country, their results would not be generalisable because patients from different

types and level of care settings usually score differently (McDowell, 2006). In order to reduce bias and/or weighting errors, I recruited patients from county hospital outpatient clinics, university hospital outpatient clinics, as well as primary care services of social security institutions (Aday and Cornelius, 2006).

Athens and Salonica were chosen because they are the two biggest cities of Greece accounting for 35.4% (3.827.000) and 10.3% (1.110.312) of the total population respectively. Kavala is an average size provincial county with a total of around 145.000 people (1.34%). These three areas together account for the 47.04% of the so called “de facto population” of 10.815.197 (Elstat, Census 2011). However, it should be taken into consideration that the real percentage is even higher than 47.04% because the number given by the Elstat census includes not only the Greek population that satisfy the inclusion criteria of this project, but also immigrants with legal or semi-legal status.

Most of the participating establishments accepted patients from the local population. However, the addresses given by respondents in the consent form show that university hospitals as well as diabetes centres in large hospitals in Athens or Salonica attract patients from all over Greece. The total number of the sites participating in the project was eight. Four of them were in Athens, three in Salonica, and one in Kavala.

“Evangelismos” of Athens was chosen as a testing site because is the biggest hospital in Greece both in terms of beds as well as number of admissions. Hippocraton of Salonica is the biggest hospital of Northern Greece. “Laiko” (Athens) is a university hospital, highly representative of the Greek diabetes population, because it is considered to be an excellent diabetes centre offering a full range of diabetes services, including a diabetic-foot clinic, serving patients from various parts of Greece and not only Athens. Also, “Alexandra” and “Polycliniki” (Athens) have been considered representative because they are very well known diabetes centres, mainly attributed to their highly respected medical personnel, serving patients outside Athens. “Kavala” is a peripheral hospital based in the city of Kavala, serving the population of the city and the prefecture of Kavala. . During the research “Kavala” hospital moved to its new buildings, where the clinic did not

have any waiting room for diabetes patients, where the administration of the questionnaire would take place. Thus, it was decided to stop the research, in order to avoid violating the rules of the questionnaire's administration.

Another four hospitals were approached: Xanthi in the Macedonia region, a hospital with characteristics and size similar to Kavala; Alexandroupolis hospital of Thrace (North-East part of Greece); Papageorgiou diabetes centre in Salonica, as well as the diabetes centre of Patras hospital (Northern Peloponnese). These hospitals were initially approached, but for a variety of reasons they did not participate in the end. Papageorgiou had the same problem with Kavala's new hospital. Patients for all clinics were waiting in the same corridor and no space was available to isolate respondents from other patients, in order to give instructions and receive reliable answers. The reason for the non-participation of Patras, Xanthi and Alexandroupolis hospitals was mainly lack of motivation of their directors.

None of the directors of the above diabetes centres were in any way acquainted to the author before the research started. After the selection of the sites was decided the contact with the directors has been succeeded with the cooperation of the Panhellenic Federation of People with Diabetes. Several personal visits to the hospitals have taken place in order to explain the aims and methods of the project and arrange the details of the procedure.

An effort was made to include branches of IKA (Social Insurance Institute) in the participating institutions. IKA is the largest social security organisation in Greece covering almost half of the Greek population. Contrary to the OGA, the agricultural workers social insurance organisation, IKA insures mostly urban population, usually manual workers from various industries.

The participants were patients with diagnosed Type 1 or Type 2 diabetes for at least one year, male and female with all possible treatment types (Insulin users, non-insulin users, on oral medication, and/or on diet only). Two exclusion criteria were used: patients aged < 18 year and patients who could not read Greek.

10.2.2 The Questionnaire

The combined questionnaire booklet consisted of four sections and 16 pages containing the three questionnaires: a two page questionnaire containing questions of demographic nature and medical parameters; the ADDQoL-Gr; a Greek version of the SF-36 and a patient consent form. The questionnaires can be found in appendices C, E, and G. The three questionnaires were bound together to be handed to respondents as one entity.

10.2.2.1 The demographic-medical questionnaire design

The first questionnaire concerned the medical and demographic characteristics of the patients. There was not any previous experience for such a questionnaire (people with diabetes) in Greece. The items have been derived from international literature, from discussions with diabetes experts and diabetes patients.

Rubin and Peyrot (1999) describe a range of factors considered by various researchers to be elements of quality of life of people with diabetes. These are: Duration and type of diabetes, any existing complications, treatment regimen, and glycaemic control. Particular attention to the role of complications was paid, because it was hypothesised to be one of the most significant medical predictor of quality of life in people with diabetes (Parkerson et al. 1993; Trief et al. 1998). Rubin and Peyrot also propose that demographic variables such as age, gender, socioeconomic status, and marital status are factors influencing QoL, thus the relevant questions were included in the questionnaire.

The layout of this questionnaire and the format of the questions was influenced by various health or diabetes-specific questionnaires (NHS 2006) and the guidelines provided by the Question Bank of the University of Essex. Also, due to its relevant simplicity it was introduced before the other two questionnaires, in order to build the necessary self-confidence in the respondent.

Special care was taken to keep questionnaire as short as possible, in order to reduce the overall length of the combined questionnaire. It contained 18 questions in four groups: 6 demographic, 3 socioeconomic, 8 medical and 1 of attitudinal nature. The demographic group asked questions about the age, gender, marital status, place of residence, time spent to reach the diabetes clinic, and educational level. The socioeconomic questions concerned the profession, monthly income, type of social security, as well as out of pocket payments of the respondent for diabetes care. In the question about profession there was a sub-question concerning the place of the respondent in the work hierarchy. Residence area and income are expected, according to the hypotheses, to play a significant role in determining quality of life.

In this questionnaire there were two questions that might have irritated the respondent, one about income (especially taking into consideration the suspicion of the average Greek about tax issues and authorities), and the other one about age. It was decided that age should not be asked directly, but as the literature suggests it should be estimated according to the year of birth (Aday and Cornelius, 2006). The exact amount of income is not necessary, thus a question about family monthly income was asked, followed by a series of income groups (*ibid*). The usual estimation of annual income that is used in the Anglo-Saxon questionnaires was not considered appropriate for cultural reasons. The notion of income to lay Greek people is related to the monthly family income. All salaries, wages, and compensations are estimated on a monthly basis. This amount supplemented by three extra benefits (the so-called bonuses, which are percentages of the monthly income), for Christmas, Easter and summer holidays constitute the annual income.

Medical questions concerned the type of diabetes, treatment regimen, duration, frequency of visiting a diabetologist and/or other relevant medical consultants, glycaemic control, any stays in hospital during the last 12 months, and the presence of any complications with the degree of severity. The medical questions have been discussed with a team of leading Greek diabetologists and a clinical psychologist.

The attitudinal question concerns the membership of the respondent to any group of people with diabetes mellitus. This question has been included in the questionnaire, following the discussion with patients, in order to assess the social

cohesion of the diabetes community in Greece and possibly create a basis for a future examination of social capital in diabetes care. Diabetes groups try to fill the gaps that the Greek NHS has in diabetes care, particularly in education and health literacy. A statistically significant positive association between such a membership and high quality of life would suggest the need to re-examine and restructure health education and diabetes care in Greece.

A final response rate of 75% would be satisfactory according to the international standards. However, due to the procedure followed the rate was a lot higher, reaching an estimated average of about 95%. A high response rate was anticipated, but the drop-out rate and the missing items, due to the length of the 3 questionnaires, were expected to mitigate the final result. 1035 patients participated in the study. However, 8 patients (0.77%) were excluded from the analyses because they had more than 6 domains missing, which according to the ADDQoL User Guidelines Rev.24.1.05A should not be tolerated. Thus, the number of respondents was 1027 for the ADDQoL. There was a high drop-out rate when respondents were reaching the SF-36 questionnaire. Out of the 1027 respondents 213 answered only part or they did not answer the questionnaire at all.

10.2.2.2 Diabetes-specific measure: the ADDQoL-Gr

There is an almost unanimous agreement among writers that for policy making and community interventions, a multidimensional assessment of QoL is necessary and that the combination of a generic and a disease-specific measures would give the best results. The use of the disease specific measure is required in order to assess the specific problems caused by the individual illness (Bowling, 1995a, 1995b; Fitzpatrick *et al.* 1998; Patrick and Deyo, 1989; Aaronson, 1988; Rubin and Peyrot, 1999; Polonsky, 2000; Snoek, 2000). Generic instruments address a wide range of issues that affect health status. They can be used for comparisons amongst various diseases as well as facilitate economic comparisons. However, despite the fact that a well-designed generic measure can assess certain quality of life dimensions, such as emotional and physical condition mobility etc, they contain items that little

relevance have to diabetes, while they lack specific items that measure other aspects of decisive importance for QoL.

A problem concerning the diabetes-specific instrument was faced from the beginning of this research, as there was not any diabetes-specific instrument translated into Greek. This problem was considered by writers as a handicap for diabetes research in Greece, but nothing had been done on the field. (Papathanasiou *et al.* 2005). The lack of translations into Greek could be attributed to the complexity of the translating process, which according to Harsimran and Bradley (2006): “*is generally underestimated ... a very time-consuming process and hence expensive*”.

Following a systematic review of the literature, the Audit of Diabetes Dependent Quality of Life (ADDQoL) was chosen as the most suitable diabetes-specific quality of life measure. The ADDQoL is the most translated diabetes-specific quality of life measure, (23 translations according to the MAPI Institute), facilitating comparisons with other countries. Thus, the Greek version of the ADDQoL (ADDQoL– Gr.) was used. The ADDQoL covers the aspects of finance, material welfare, sexual functioning and independence, mentioned above. The overall advantages of ADDQoL as a diabetes-specific measure *per se* have been discussed in the relevant chapter of the literature review.

10.2.2.3 Generic measure: The SF-36

The SF-36 is a generic instrument that assesses the impact diabetes has on every day's life of the patient. It is a burden-type instrument. The SF-36 is the most widely used generic measure in diabetes quality of life studies (Luscombe, 2000; Rubin and Peyrot, 1999). Also, the SF-36 domains are mostly relevant to people with diabetes and the level of detail of responses is more appropriate for them than other generic measures such as the NHP (Bradley, 1996).

However, the ADDQoL does not assess the burden, but how diabetes interferes with the perceived well-being of the patient. Research has proved that the two measures

can be used in a complementary manner (Woodcock *et al.* 2001). The idea of its use in relation with the SF-36 is strengthened even further by the ascertainment that the ADDQoL can differentiate between those with and without diabetic co morbidity. It has been reported that the ADDQoL scores are not significantly affected by non-diabetic co-morbidity (*ibid*).

The SF-36 was used as the generic measure The SF-36 is a generic health survey comprising of 36 questions scored in eight dimensions. It is the most widely used instrument worldwide and according to its owners, it has been translated into 140 languages (QualityMetric 2012). Garratt *et al.* (2002a) reviewed 3921 evaluation reports and they reported that the SF-36 is the most evaluated measure, accounting for the 10% of the total number of the reviewed reports. This may be attributed to the fact that the SF-36 is more sensitive to lesser degrees of dysfunction, as it is the case with diabetes, than other measures such as the NHP.

The SF-36 has been proved to be a valid and reliable instrument, with 17,000 published studies in the last 20 years. Although it is health status measure, researchers use it implicitly as a proxy measure of QoL.

As it has already been said there is no “gold standard” in the field of QoL research, but the SF-36 has achieved such a high status among researchers, that it is sometimes referred as the “gold standard” for health status instruments. (Michalos *et al.* 2000). Nevertheless, the SF-36, as a generic measure, is not enough to tap very important issues of chronic illnesses, such as finances, material welfare, sexual functioning, communication, independence etc. (Bowling, 1995b).

Another issue with generic measures that should not escape one’s notice is that the relative importance that patients ascribe to various domains of QoL shows considerable variation in relation to the disease. The prioritization of domains for people with diabetes, for example, is different to people with mental health problems (Bowling, 1996). Generic measures do not seem to be sensitive in detecting differences in lifestyle as well as in the perception of life by the patient (Jacobson, 1994; McColl *et al.* 1995). As far as diabetes is concerned, the aspects of dietary restrictions, sexual functioning, independence, fear of hypoglycaemia,

and type of treatment regimen are of major importance, but not tapped by the SF-36.

The SF-36 has already been translated and validated into Greek (Pappa *et al.* 2005; Anagnostopoulos *et al.* 2005). Permission for the use of the SF-36v2 Health Survey in this study has been obtained from the owners QualityMetric.

10.2.3 Ethical Approval

There is no ethical committee at national level responsible for this kind of research. Ethical approval was obtained from the management of the hospitals, which in turn had to ask the ethical committee operating in each hospital. To this end an initial verbal contact was made with the selected hospital authorities in order to explain the intention of the study, the period involved, and what will be required from the patients and hospital staff. This conduct was followed by a letter confirming what was already discussed and this letter was followed by an official written application to hospitals' governors that was made by the diabetologists of the centres. This bureaucratic process was considered necessary because the management can give permission for research only to hospital's personnel and not outsiders.

10.2.4 The survey

The questionnaire was delivered to patients for completion during the waiting time of a regular clinic visit. In this respect, within each care unit it was a convenience sample. The administration took place on face-to-face basis. This sort of administration represents the "gold standard" in questionnaire surveys (Jackle *et al.* 2006). The waiting time is usually long, because the system does not operate with appointments but on a "first-come, first-served" basis. The patients arrive before the administrative staff starts its shift at 07.30 hrs, they pay their co-payment fee and wait in a lounge for the physicians, who start seeing patients at 09-09.30 hrs. During this long waiting time the questionnaire was administered, thus there was

substantial time to answer the questions and at the same time it was an interesting occupation for the patients.

The investigator and/or the diabetes nurse, or the diabetes psychologist in the case of Polycliniki, provided patients with oral and written information about the title, the nature, and the aim of the project, explained to them the purpose and the importance of the study, as well as what their participation involves, and asked them to participate. The patients were also informed about the unique value of their views, the voluntary nature of their participation, confidentiality, and that a refusal to participate or withdrawal from the study would not affect in any way the quality of care they are going to receive. Patients were given the opportunity to ask questions about the research, as well as enough time to consider the answers provided.

Upon their agreement, the patients were asked to confirm their voluntary participation by signing a consent form, which constituted the first page of the questionnaire (Appendices I and J). The consent form was containing the title of the study, the test-site number, and a patient's identification number which was filled by the administrator.

Information concerning the content of the questionnaires was provided and the patient was asked to respond to three statements. The first was that they had read and understood the information sheet and they agreed to participate. The second statement concerned the voluntary nature of their participation and the fact that they could withdraw at any time without any impact on their medical care. The third one was their agreement to communicate with them in the future asking them for their personal details. The patients could be asked to participate in the future in case the responsiveness of the ADDQoL-Gr would be examined.

Participants were asked to fill the questionnaires under complete confidentiality within the health care establishment. Help in clarifying questions about the questionnaire's completion was offered upon request. Those who finally accepted to participate were handed the 16 pages questionnaire booklet.

Any reference to the Federation of People with Diabetes Mellitus, the secondary organisation of diabetes-patients groups that helped throughout this project was systematically avoided. This was decided because responses may be distorted by the general tendency of the respondents to conform to “social desirability” (Veenhoven, 2002). Social desirability is the tendency of respondents to reply in a manner viewed favourably by others. The Federation is well known and highly esteemed among patients with diabetes and there is a possibility that answers would agree with the Federation on various issues. In such a case bias would be observed resulting to strong floor and ceiling effects. Last, special care was taken to avoid the physician’s presence as well as the presence of any spouses. In teaching hospitals it was ensured that no research involving people with diabetes was taking place.

Data collection started in June 2010 and was finished by February 2011.

10.3 Results

A total of 1027 diabetes-patients participated in the survey from eight different sites. The demographic and socioeconomic characteristics are presented in Table 6. Diabetes-related characteristics of the sample are presented in Table 7.

The demographic characteristics of the sample is similar in many respects to those of the total Greek population, especially when age is taken into consideration. The mean age of the sample was 58.2 ± 16.1 . Although the mean age of Greek nationals is 42.6 years (Eurostat, 2011) the higher age of the sample was expected because: a) it excluded people under 18, a population accounting for the 19.63% of the total, and b) the majority of the sample (72.3%) is made up of people with type 2 diabetes who in most cases are over the age of 45. Thus, the 72.3% of the sample does not include patients between 19 and 45, an age group that accounts for the 35.32 of the total Greek population. Because of these two reasons the mean age of the sample is higher than the total population’s mean. Also, it should be noted that the mean age of 58.2 is in consistent with reports of diabetes instruments from different countries.

(Jacobson et al, 1994: Mean age 44 for type 1 diabetes and 60 years for type 2; Welch et al., 1997: 41.6 years of age for type 1 and 63.2, 63.9, 66.6 years for various groups of type 2 patients; Anderson et al. 1997: 63.4 years ; Bradley et al., 1999: 61.6 and 52.4 years for the two sites of research).

Female respondents represent 58.9% of the total sample, which is higher than the national average of 51% (Elstat, 2013). This difference might be attributed to two reasons: a) the national average percentage includes immigrants, the majority of whom are males, lowering the national female average. (Triantafyllidou, 2009: Immigration towards Greece at the Eve of the 21st Century. A Critical Assessment. Zoumpopoulou b) the sample has a mean age higher than the national average because of the preponderance of type 2 diabetes patients who are above this average. After the age of 45, in all 5-years bands, the majority of the population is female, with the difference between the genders increasing as age increases.

Unmarried people in Greece are 24.3% of the total population, while the same category in the sample accounts for 19%. The percentage of married/partner people of the sample is almost identical that of the general public with 61.9% and 61.6% respectively. Widow/ers account for 13.3% of the sample, which is considered satisfactory compared with a 9.44% of total population and 19.13% of the population over 50 years of age (type 2 diabetes margin).

As far as level of education is concerned the sample is representative with 38.1% of respondents with primary education, compared with 36.8% in the Greek population, respondents with secondary education 14.5% of the sample compared with 11.3% in the national population; Lyceum Apolytirion holders made up 25.9% of the sample compared with 26.2%, and finally University graduates were 20.6% of the sample with a Greek average of 15.4% (Elstat, 2011).

Table 6: Demographic & Socioeconomic characteristics of the sample

Testing site	n (%)
IKA Thessalonikis 1	213 (20.7%)
IKA Thessalonikis 2	47 (4.6%)
Hippokration Thessalonikis	264 (25.7%)
Polikliniki Athens	89 (8.7%)
Laiko Athens	60 (5.8%)
Evangelismos Athens	194 (18.9%)
Alexandras Athens	96 (9.3%)
Kavala	64 (6.2%)
Total	1027(100%)
Gender	
Male	420 (40.9%)
Female	605 (58.9%)
Missing	2 (0.2%)
Age (years) mean±SD	58.2±16.1
median (min-max)	62.0 (15.0-89.0)
Family status	
Unmmaried	195 (19.0%)
Married/partner	636 (61.9%)
Divorced	57 (5.6%)
Widow/er	137 (13.3%)
Missing	2 (0.2%)
Education	
Primary school	391 (38.1%)
Secondary	149 (14.5%)
Lyceum	266 (25.9%)
University	212 (20.6%)
Missing	9 (0.9%)
Monthly salary (€)	
0-500	199 (19.4%)
501-1000	305 (29.7%)
1001-1500	275 (26.8%)
1501-2000	100 (9.7%)
2001-2500	43 (4.2%)
2501-3000	25 (2.4%)
>3000	34 (3.3%)
missing	46 (4.5%)

Table 7: Diabetes related characteristics of the sample

Diabetes Type	n (%)
I	281 (27.4%)
II	743 (72.3%)
missing	3(0.3%)
Age when diagnosed with diabetes(years)	mean±SD 43.3±18.5 median (min-max) 48.0 (1.0-80.0)
HbA_{1c} (%)	
6.5-7.0	382 (37.2%)
7.0-7.5	251 (24.4%)
7.5-8.0	163 (15.9%)
8.0-8.5	84 (8.2%)
8.5-9.0	43 (4.2%)
>9.0	56 (5.5%)
missing	48 (4.7%)
Treatment	
Insulin	533 (51.9%)
Oral medication	461 (44.9%)
Diet	31 (3.0%)
missing	2 (0.2%)
Complication of Diabetes	
Yes	303 (29.5%)
No	717 (69.8%)
missing	7 (0.7%)
Frequency of doctor/clinic visit	
Every month	226 (22.0%)
Every 3 months	591 (57.5%)
Every 6 months	147 (14.3%)
Every year	44 (4.3%)
Every 2 years	17 (1.7%)
missing	2 (0.2%)
Specialty	
Cardiologist	536 (52.2%)
Eye doctor	348 (33.9%)
Kidney doctor	14 (1.4%)
Podiatrist	3 (0.3%)
Psychiatrist/psychologist	6 (0.6%)
missing	120 (11.7%)
Hospital Visit the last year	
Yes	24 (2.3%)
No	797 (77.6%)
missing	6 (0.6%)
Expenses for diabetes (last 2 months)	
0-50	289 (28.1%)
50-100	389 (37.9%)
100-150	162 (15.8%)
150-200	46 (4.5%)
200-250	32 (3.1%)
250-300	27 (2.6%)
>300	73 (7.1%)
missing	9 (0.9%)
Member of a diabetes association	
Yes	92 (9.0%)
No	930 (90.6%)
missing	5 (0.5%)

The sample is not homogeneous among the testing sites. Tables 8 and 9 present the differences according to demographic and diabetes-related characteristics respectively. There are statistically significant differences showing that each diabetes centre, although typically open to anyone, attracts some special groups of patients. Polycliniki for example has the majority of patients with type 1 diabetes followed by Evangelismos. This was an unexpected result and had to be discussed with the directors of the diabetes-centres. The cause for this according to them was that, out of their own initiative, they have created some diabetes-education courses for type 1 patients, who afterwards continue visiting the centre on a permanent basis.

There are also statistically significant differences among testing sites concerning the age and educational level of the patients. Polycliniki and Evangelismos, compared with other hospitals, attract younger, unmarried, most educated patients, as well as patients with an early diabetes onset. These differences should be expected because of the high percentage of type 1 patients in their samples. Laiko, Evangelismos, and Polycliniki attract more male patients compared with other hospitals.

Significant differences are also observed between hospital samples and the monthly salary of the patients. Polycliniki and Laiko attract people with higher income, while Kavala's patients report the lowest income.

Polycliniki, Laiko, and Evangelismos seem to gather high percentages of people treated with insulin, while Laiko, Evangelismos, and Kavala hospitals have the highest numbers of patients with diabetes complications. Laiko, Kavala and Hippokration have high percentages of people who were hospitalised for any reason during the period of twelve months before the survey.

Table 8: Sample differences among testing sites (Demographic)

Testing Site *	Gender			Mean Age	Income in € (Mean)	Family Status (p<0.0001)				Educational Level (p<0.0001)			
	Male	Female	Total			Single	Married/partner	Divorced	Widow/er	Primary School	Gymnasium	Lyceum	Higher
1	81	132	213	61.99	2.91	24	119	14	55	85	41	60	21
	a:38	a:62.0	a:100			a:11.3	a:56.1	a:6.6	a:25.9	a:41.1	a:19.8	a:29.0	a:10.1
	b:19.3	b:21.8	b:20.8			b:12.3	b:18.7	b:24.6	b:40.1	b:21.7	b:27.5	b:22.6	b:9.9
2	17	30	47	67.19	2.71	2	39	0	6	29	2	10	6
	a:36.2	a:63.8	a:100			a:4.3	a:83.0		a:12.8	a:61.7	a:4.3	a:21.3	a:12.8
	b:4.0	b:5.0	b:4.6			b:1.0	b:6.1		b:4.4	b:7.4	b:1.3	b:3.8	b:2.8
3	102	160	262	61.57	2.19	34	187	11	31	136	31	54	41
	a:38.9	a:61.1	a:100			a:12.9	a:71.1	a:4.2	a:11.8	a:51.9	a:11.8	a:20.6	a:15.6
	b:24.3	b:26.4	b:25.6			b:17.4	b:29.4	b:19.3	b:22.6	b:34.8	b:20.8	b:20.3	b:19.3
4	42	47	89	43.89	4.07	36	45	6	2	6	8	30	45
	a:47.2	a:52.8	a:100			a:40.4	a:50.6	a:6.7	a:2.2	a:6.7	a:9.0	a:33.7	a:50.6
	b:10.0	b:7.8	b:8.7			b:18.5	b:7.1	b:10.5	b:1.5	b:1.5	b:5.4	b:11.3	b:21.2
5	34	26	60	55.50	3.33	14	39	2	5	7	10	18	25
	a:56.7	a:43.3	a:100			a:23.3	a:65.0	a:3.3	a:8.3	a:11.7	a:16.7	a:30.0	a:41.7
	b:8.1	b:4.3	b:5.9			b:7.2	b:6.1	b:3.5	b:3.6	b:1.8	b:6.7	b:6.8	b:11.8
6	94	100	194	52.88	2.58	68	90	15	21	52	27	64	51
	a:48.5	a:51.5	a:100			a:35.1	a:46.4	a:7.7	a:10.8	a:26.8	a:13.9	a:33.0	a:26.3
	b:22.4	b:16.5	b:18.9			b:34.9	b:14.2	b:26.3	b:15.3	b:13.3	b:18.1	b:24.1	b:24.1
7	32	64	96	56.41	2.57	13	67	6	10	28	21	24	22
	a:33.3	a:66.7	a:100			a:13.5	a:69.8	a:6.3	a:10.4	a:29.5	a:22.1	a:25.3	a:23.2
	b:7.6	b:10.6	b:9.4			b:6.7	b:10.5	b:10.5	b:7.3	b:7.2	b:14.1	b:9.0	b:10.4
8	18	46	64	66.90	1.89	4	50	3	7	48	9	6	1
	a:28.1	a:71.9	a:100			a:6.3	a:78.1	a:4.7	a:10.9	a:75.0	a:14.1	a:9.4	a:1.6
	b:4.3	b:7.6	b:6.2			b:2.1	b:7.9	b:5.3	b:5.1	b:12.3	b:6.0	b:2.3	b:0.5

* Testing Sites 1: IKA Salonica 1; 2: IKA Salonica 2; 3: Hippokration Salonica; 4: Polycliniki Athens; 5: Laiko Athens; 6: Evangelismos Athens; 7: Alexandra Athens; 8: Kavala

a: % within testing site sample; b: % within total sample

Table 9: Sample differences among testing sites (Diabetes-related)

Testing Site *	Diabetes Type (p<0.0001)		Diabetes onset age (p<0.0001)	Treatment p<0.0001			Complications p<0.0001		Hospitalisation p=0.003	
	1	2		Insulin	Oral med	Diet	No	Yes	No	Yes
1	43	170	47.77	93	110	10	165	48	169	44
	a: 20.2	a:79.8		a:43.7	a:51.6	a:4.7	a:77.5	a:22.5	a:79.3	a:20.7
	b:15.3	b:22.9		b:17.4	b:23.9	b:32.3	b:23.0	b:15.8	b:21.2	b:19.6
2	2	45	54.48	11	36	0	35	12	38	9
	a:4.3	a:95.7		a:23.4	a:76.6	a:0	a:74.5	a:25.5	a:80.9	a:19.1
	b:0.7	b:6.1		b:2.1	b:7.8	b:0	b:4.9	b:4.0	b:4.8	b:4.0
3	37	225	47.63	130	129	5	180	79	186	74
	a:14.1	a:85.9		a:49.2	a:48.9	a:1.9	a:69.5	a:30.5	a:71.5	a:28.5
	b:13.2	b:30.3		b:24.4	b:28.0	b:16.1	b:25.1	b:26.1	b:23.3	b:33.0
4	62	27	27.14	71	16	2	70	19	76	13
	a:69.7	a:30.3		a:79.8	a:18.0	a:2.2	a:78.7	a:21.3	a:85.4	a:14.6
	b:22.1	b:3.6		b:13.3	b:3.5	b:6.5	b:9.8	b:6.3	b:9.5	b:5.8
5	19	41	38.43	44	14	1	24	36	42	18
	a:31.7	a:68.3		a:74.6	a:23.7	a:1.7	a:40.0	a:60.0	a:70.0	a:30.0
	b:6.8	b:5.5		b:8.3	b:3.0	b:3.2	b:3.3	b:11.9	b:5.3	b:8.0
6	89	105	36.18	123	65	6	135	59	162	32
	a:45.9	a:54.1		a:63.4	a:33.5	a:3.1	a:69.6	a:30.4	a:83.5	a:16.5
	b:31.7	b:14.1		b:23.1	b:14.1	b:19.4	b:18.8	b:19.5	b:20.3	b:14.3
7	23	72	44.19	31	60	4	75	19	80	14
	a:24.2	a:75.8		a:32.6	a:63.2	a:4.2	a:79.8	a:20.2	a:85.1	a:14.9
	b:8.2	b:9.7		b:5.8	b:13.0	b:12.9	b:10.5	b:6.3	b:10.0	b:6.3
8	6	58	50.21	30	31	3	33	31	44	20
	a:9.4	a:90.6		a:46.9	a:48.4	a:4.7	a:51.6	a:48.4	a:68.8	a:31.3
	b:2.1	b:7.8		b:5.6	b:6.7	b:9.7	b:4.6	b:10.2	b:5.5	b:8.9

* Testing Sites 1: IKA 1 Salonica ; 2: IKA 2 Salonica; 3: Hippocraton Salonica; 4: Polycliniki Athens; 5; Laiko Athens;

6: Evangelismos Athens; 7: Alexandras Athens; 8: Kavala

a: % within testing site sample; b: % within total sample

Chapter 11: Validation of the ADDQoL-Gr

11.1 Introduction

The principal aim of these analyses is to assess the QoL of people with diabetes in Greece as well as to identify the factors that determine the QoL concept. To this end the ADDQoL was selected as the main research instrument. However, it is well established that the validity of a measure is “*not an once and for all*” attained property, neither is it an “*all-or-none*” property (Streiner-Norman, 2008; Nunnally-Bernstein, 1994). Moreover, validity issues become more complicated when the instrument has to be translated into another language in order to be used with people of another culture. Bradley (1996) epitomised the problem with the phrase: “*the psychometric properties cannot be assumed to travel well*”.

Thus, in order to examine whether the translated and culturally adapted instrument has kept all its original properties, as well as the applicability of the ADDQoL-Gr to the Greek diabetes population, the first statistical procedure should address the psychometric properties of the measure.

11.2 Methods

The data collected were subjected to factor analysis. An Explanatory Factor Analysis was performed for the 19 items ADDQoL-Gr using a two-step approach of Principal Components Analysis (PCA) with varimax rotation. The two overview items were not included in the analysis, as these items receive a different treatment and are examined as separate items. “Not Applicable” responses were recoded as zero (Bradley, 2007).

Reliability (internal consistency) of the ADDQoL-Gr. was assessed by Cronbach’s alpha. The results were compared with the original study’s results (Bradley *et al.* 1999). Item-total correlation was also assessed.

Various types of Validity were examined. Criterion Validity, in its Concurrent form, was assessed against SF-36. There are no comparable results with this validation process, but respondents with moderate or severe problems on SF-36 are expected to have worse scores on the ADDQoL. Construct Validity was evaluated against the two global questions of the ADDQoL-Gr. It was also evaluated in the form of the Discriminative (or known groups) validity, using the different types of treatment as criterion. Face and Content Validities were examined throughout this research starting from the translation and continuing with interviews with patients and experts.

11.3 Results

11.3.1 Factor Analysis

Factor analysis performed for ADDQoL-Gr, using listwise deletion of missed data. Unforced factor analysis with varimax rotation on the weighted ADDQoL scores generated three factors with eigenvalues greater than 1. The Kaiser-Guttman rule, which mostly used in analyses, factors with eigenvalues greater than 1 should be retained (Nunnally-Bernstein, 1994).

The factor loadings were generally high. The magnitude of the loading that is acceptable for items to define a factor is heuristically accepted as ≥ 0.40 (Ferguson and Cox, 1993). Others believe that the lower limit is 0.30. According to Streiner and Norman (2008) loadings between 0.30 and 0.60 are considered to be moderately high and loadings greater than 0.60 are considered as high. Factor loadings <0.4 have not been displayed in Table 10.

Fourteen of the 19 domains loaded greater than 0.4 on factor 1. 13 of them loaded on factor 1 with no cross-loading on any other of the other two factors. Cross-loading is defined as having factor loading of at least 0.40 on more than one factor with a difference between the two loadings of 0.20. The “Close personal relationship” item loaded on two factors with a loadings difference marginally above 0.20. Four items

(work, holidays, personal relationship and sexual life) loaded highly on factor 2. The items freedom to eat and freedom to drink loaded highly onto Factor 3.

A three-factor solution explained 54.0% of variance. The results suggest that a substantial proportion of items load together on the first factor, though additional clusters are apparent.

Table 10: Factor Loadings from unforced factor analysis with varimax rotation on the weighted ADDQoL-Gr scores.

Domains	Factor Loadings		
	Factor 1	Factor 2	Factor 3
Motivation	0.769		
Physical health	0.731		
Local or long journeys	0.707		
Self-confidence	0.705		
Leisure activities	0.693		
Living condition	0.680		
Physical appearance	0.670		
Friendship and social life	0.650		
Feelings about the future	0.635		
Family	0.620		
Financial situation	0.600		
People's reaction	0.563		
Dependence on others	0.519		
Sexual life		0.742	
Work		0.685	
Close personal relationship	0.426	0.662	
Holiday		0.498	
Freedom to drink			0.852
Freedom to eat			0.803

When other factors were disallowed with a forced one-factor solution, 17 out of the 19 domains loaded greater than 0.5 on the factor. "Freedom to eat" was less than 0.5 and "freedom to drink" and "work" had the lowest loadings of less than 0.4. It should be noted that more than half of the patients (61.5%) responded as Non Applicable regarding the domain 'work', therefore this loading should be expected.

By removing the item ‘work’ and rerunning the analysis it was observed that the amount of variance explained was increased to 42.7%. Despite its low loading, freedom to drink was still within the acceptable lower limit of >0.30 (Kline, 1994; Streiner and Norman, 2008). Also, the item should be retained as a domain, as 51.3% of the patients indicated that their “freedom to drink” was “important” to “very important” to them. The forced one-factor solution explained 41.1% of the variance (Table 11). The above results support the fact that the computation of the Average Weighted Impact (AWI) represents the mean of the ADDQoL-Gr applicable domains and could be treated as a QoL outcome measure.

Table 11: Factor Loadings from one forced factor analysis on the weighted ADDQoL.

Domains	Loadings
Motivation	0.788
Living condition	0.776
Self-confidence	0.754
Friendship and social life	0.744
Physical health	0.737
Feelings about the future	0.724
Family	0.719
Financial situation	0.681
Local or long-distance journeys	0.670
Close personal relationship	0.667
Leisure activities	0.663
People’s reaction	0.638
Physical appearance	0.624
Holidays	0.574
Dependence on others	0.513
Sexual life	0.511
Freedom to eat	0.415
Work	0.364
Freedom to drink	0.361

In conclusion, factor analysis findings support the one-factor scale structure of the ADDQoL. However, “strict unidimensionality” of the instrument, in the sense of one

dominant latent variable with no secondary minor dimensions, does not exist. It is apparent that the instrument, with 14 items loading on one factor, demonstrates “essential dimensionality”, that is the instrument has one dominant factor with the inclusion of underlying secondary minor factors (Slocum-Gori *et al.* 2009; Slocum-Gori and Zumbo, 2011).

11.3.2 Reliability Analysis of the ADDQoL-Gr

11.3.2.1 Internal Consistency

11.3.2.1.1 Cronbach's α

Cronbach's α and item-total correlation were used to assess internal consistency of the ADDQoL-Gr.

Cronbach's α for the ADDQoL-Gr was estimated at 0.915. The original 12 items measure showed $\alpha = 0.846$ (Bradley *et al.* 1999), the 18 item instrument showed $\alpha = 0.92$ (Bradley and Speight, 2002). Other translations showed alphas of 0.89 (Costa *et al.* 2006), 0.94 (Wee *et al.* 2006, Kamarun Imran *et al.* 2007). At first site an α over 0.90 suggests that the instrument could be shortened without losing its reliability. On the other hand, according to Streiner and Norman (2008) a scale of more than 11 items and a sample of over 300 should have an α of 0.90 in order to be called “good”, thus the ADDQoL-Gr with 0.915 appears to have an excellent α .

11.3.2.1.2 Item-total correlation

The values in the column Corrected Item-Total Correlation are the correlations between each item and the total score from the questionnaire. All items show an item-total reliability well above the limit of 0.20, which Streiner and Norman (2008) cite as “the usual rule of the thumb” according to which all items below that limit should be discarded.

Items for work, freedom to eat and freedom to drink had the lowest correlation with the overall score from the scale, but not so low that will need to be dropped in order to increase the degree of reliability or to necessitate a second factor. The values in the column “Cronbach’s Alpha if Item Deleted” are around 0.915 (the overall α). Only freedom to drink and freedom to eat had greater value of α than the overall α , showing once more the distinctiveness of these two items, but this difference is only marginal.

Table 12: Item-Total Statistics

Domain	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Cronbach's Alpha if Item Deleted
Leisure Activities	-43.53	960.704	0.603	0.910
Work	-44.64	1000.242	0.326	0.916
Local or long journeys	-43.31	952.147	0.610	0.909
Holiday	-43.58	959.704	0.526	0.911
Physical health	-42.93	934.731	0.677	0.908
Family life	-42.93	929.721	0.663	0.908
Friendship and social life	-43.79	931.237	0.693	0.907
Personal relationship	-43.75	939.014	0.614	0.909
Sex life	-43.99	966.984	0.461	0.913
Physical appearance	-44.07	962.841	0.562	0.911
Self-confidence	-43.18	926.937	0.702	0.907
Motivation	-43.30	920.021	0.729	0.906
People's reaction	-44.50	966.716	0.583	0.910
Feelings about the future	-42.58	923.567	0.670	0.908
Financial situation	-43.56	938.658	0.627	0.909
Living condition	-43.25	918.304	0.726	0.906
Dependence on others	-43.15	963.008	0.454	0.913
Freedom to eat	-41.40	969.892	0.380	0.916
Freedom to drink	-43.41	985.691	0.335	0.916

11.3.3 Validity

11.3.3.1 Construct Validity

Construct validation of an instrument seeks agreement between a theoretical concept and a specific measurement. It addresses two properties of the measure: first, its ability to measure what it purports to measure, and second its suitability for its pre-defined purpose (Williams and Naylor, 1992). Construct validity of the ADDQoL-Gr was examined by correlating the average weighted average of the ADDQoL-Gr with the two global single-item questions.

Before the various forms of validity were assessed some hypotheses should be generated:

- The scores of the AWI and the global (diabetes-related) question 2 of the ADDQoL should correlate strongly, because they address the same attribute;
- The correlations scores of the AWI and the global question 1 about “present general QoL” of the ADDQoL should be weak to moderate, because the AWI is disease-specific and global question 1 is of a generic nature;
- The correlations of the AWI and the component summary scores of the SF-36 should be weak to moderate for the same reason as above;
- The correlations of the global question 1 about “present general QoL” should correlate strongly with the Component Summary Scores of the SF-36, because they are both generic measures;
- The correlations of the weighted impact scores of the ADDQoL 19 items with the 8 health dimensions of the SF-36 should be moderate for the domains that could be considered relevant, and weak for the QoL domains of the ADDQoL that the SF-36 does not tap;
- Respondents with complications and insulin users should report lower levels of QoL.

Corroboration of these hypotheses would be a strong indication of the ADDQoL-Gr validity.

11.3.3.1.1 Discriminant - Convergent Validity

These two types of validity, convergent and discriminant validity are grouped together because, although different in terminology, because they represent the two extremes in a continuum of associations between the dimensions of QoL. (Fayers and Machin, 2007).

First, the mean weighted ADDQoL score were correlated with the two single-item measures of the questionnaire. Spearman's rank correlation coefficient (ρ) was used to test this association. Spearman's correlation, instead of Pearson's, was used because the Kolmogorov-Smirnov test showed that the distribution was not normal. Cohen's conventions were used to interpret the results: any correlation greater than 0.5 is large, 0.3-0.5 is moderate, 0.1-0.3 is small, and anything smaller than 0.1 is insubstantial (Cohen, 1992). It was hypothesised that ADDQoL should correlate better with global question 2.

As hypothesised, average weighted ADDQoL score was better correlated with the rating of quality of life without diabetes ($r = 0.57$, $p < 0.0001$) than to the present quality of life ($r = 0.37$, $p < 0.0001$). The relative values of the original instrument were $r = 0.31$ for the first question concerning the present QoL, and $r = 0.47$ for the second question i.e. for life without diabetes (Bradley *et al.* 1999).

The fact that the mean weighted ADDQoL-Gr score is stronger related to the single-item question 2 of the questionnaire, which refers to the diabetes dependent QoL, than to the question 1 about general QoL, might be considered as a strong indication for the existence of discriminant validity.

Last, it should be noted that although both these correlations are highly significant, they are well below 1 indicating that the total ADDQoL-Gr scale provides information additional to that elicited from the two global questions.

11.3.3.2 Criterion Validity

Criterion validity is the correlation of a scale whose interpretation is under question (target instrument) with some other measure used as criterion (anchor) (Guyatt et al., 2002). It is used to demonstrate the accuracy of a measure by comparing it with another, which has been used and accepted as being valid. This criterion measure ideally acts as a “gold standard” (Streiner and Norman, 2008). At this point it should be noted that criterion validity is conceptually the same with construct validity and the two differ only in methodological terms (*Ibid*). Criterion validity should be considered as a “subcategory” of the construct validity (McDowell, 2006).

Criterion validity was examined in its concurrent form. Concurrent validity is the corroboration that an instrument is measuring what it purports to measure against a criterion measure, which acts as a “gold standard”. The two measures should be administered at the same time. In this study criterion validity was examined against the SF-36, which was administered simultaneously with the ADDQoL-Gr. The correlations between the Summary Components of the SF-36 and the ADDQoL-Gr Aggregate Scores are shown in table 13.

Table 13: Spearman’s correlations between ADDQoL and SF-36 Summary Components

ADDQoL Aggregate Scores	SF 36 Component Summaries	
	Physical Component Summary	Mental Component Summary
Average Weighted Impact	0.349	0.345
Present QoL in general	0.540	0.488
Diabetes Related QoL	0.163	0.171

The validity of the ADDQoL is supported by the fact that although the single-item global question about general QoL correlates strongly with both Physical and Mental components of the SF-36 (0.540 and 0.488), the AWI of the ADDQoL-Gr has a medium correlation with the summary components of the SF-36 (0.349 and 0.345), indicating that the two instruments measure similar but not identical concepts (Table 13). There is some degree of overlapping between the two constructs, but they are

not redundant in any sense. The result proves that the ADDQoL-Gr provides a more targeted measure for diabetes than the SF-36.

This was expected because although health status and HRQoL are similar concepts they are not identical. Thus, these results have a twofold use: they support the criterion validity of the ADDQoL-Gr, and at the same time they might be a contribution to the continuing discussion about the suitability of health status measures for measuring QoL.

Another point worth mentioning emerges by observing the low correlations between the single-item question of the ADDQoL-Gr (Diabetes-Related-QoL), and the SF-36 Summary Components. These correlations compared with the medium correlations of the Average Weighted Impact show the gain in sensitivity of the 19 item weighted instrument compared with the unweighted single item question. This finding might be useful in the single versus multi-item instruments discussion mentioned in Chapter 4.

Some of the ADDQoL-Gr domains are relevant to the SF-36 dimensions, while some others are not relevant at all. The dimension of pain for example is not a domain in diabetes patients, while “sex life”, “freedom to eat” or “drink” are not assessed by SF-36. In Table 14 the domain Bodily Pain (BP) has, as expected, the lowest correlation coefficients with the ADDQoL items. Also, the items “close personal relations” and “sex life” “freedom to eat” and “freedom to drink” have very low correlation coefficients with SF-36 domains.

On the other hand the domains of the ADDQoL that could, with some heuristic degree of freedom, be considered relevant to SF-36 dimensions should have medium correlations coefficients. Thus, as expected “journeys”, “physical health”, “physical appearance” of the ADDQoL, appear to correlate well with the “general health”, “physical functioning”, “role physical” and “vitality” of the SF-36.

However, some expected correlations do not appear in the table. For example, it could be considered that “social life” domain of the ADDQoL, should be reflected in the “social functioning” dimension of the SF-36. Also, “feelings about the future”,

“self-confidence”, and “motivation”, should be correlated with “mental health (MH)” of the SF-36. For reasons that probably need further investigation this is not the case. The MH domain has low correlations with all of the ADDQoL dimensions. The same happens with the role emotional (RE) domain of the SF-36.

Table 14: Spearman’s correlations between ADDQoL-Gr item and SF-36 domain scores (N=814)

ADDQoL Items	SF-36 domains							
	GH	PF	RP	BP	VT	SF	RE	MH
Leisure	0.240	0.225	0.286	0.149	0.258	0.287	0.246	0.233
Work	-0.016	-0.206	-0.058	-0.095	-0.100	-0.017	-0.035	.026
Journeys	0.342*	0.328*	0.338*	0.253	0.318*	0.358*	0.232	0.216
Holiday	0.100	0.019	0.103	0.063	0.068	0.082	0.080	0.081
Physical health	0.346*	0.359*	0.364*	0.261	0.364*	0.385*	0.266	0.267
Family life	0.222	0.227	0.263	0.168	0.243	0.292	0.264	0.236
Social life	0.266	0.269	0.255	0.119	0.219	0.279	0.225	0.207
Personal relations	0.089	0.077	0.092	0.011	0.068	0.139	0.154	0.143
Sex life	-0.028	-0.086	0.003	-0.054	-0.032	0.035	0.038	0.047
Phys. appearance	0.281	0.342*	0.323*	0.216	0.278	0.330*	0.286	0.221
Self confidence	0.291	0.219	0.256	0.183	0.233	0.262	0.258	0.232
Motivation	0.260	0.232	0.223	0.184	0.209	0.267	0.217	0.208
People’s reaction	0.173	0.175	0.191	0.147	0.175	0.191	0.156	0.162
Future worries	0.230	0.181	0.222	0.144	0.154	0.232	0.214	0.172
Financial situation	0.192	0.211	0.214	0.193	0.182	0.211	0.209	0.190
Living condition	0.206	0.218	0.196	0.112	0.194	0.247	0.293	0.224
Dependence	0.220	0.165	0.191	0.169	0.155	0.193	0.179	0.191
Freedom to eat	0.200	0.208	0.164	0.122	0.158	0.207	0.112	0.096
Freedom to drink	0.079	0.059	0.086	0.007	0.059	0.112	0.050	0.083

*indicates moderate correlation

11.3.3.3 Discriminative (or known groups) validity

Discriminative validity refers to whether a scale is able to differentiate between two groups with different traits (Streiner and Norman 2008). It is based on the hypothesis that certain groups of patients are supposed to score differently than other groups (Fayers and Hand, 2002).

Discriminative validity of the ADDQoL-Gr is supported by comparing the scores reported by insulin-treated patients with the oral medication-treated ones. The Kruskal Wallis test revealed that there was a statistically significant difference in the means of weighted ADDQoL scores between the type of therapy ($p < 0.05$). Patients treated with insulin had significantly lower ADDQoL Average Weighted Impact (AWI) score (-2.78), compared with those treated with tablets (-2.44).

Known groups validity was further supported by comparing the AWI scores of people who reported at least one complication with those without any complication caused by diabetes. As hypothesised the first group reported statistically significant lower levels of QoL (-3.36 and -2.30 respectively).

11.3.3.4 Content and face validity

Content and face validity, are to a great extent informal types of validity which depend mainly on value judgements. The assessment of both of these types was an ongoing procedure throughout this research. It started during the forward translation phase of the ADDQoL, continued with the discussions with experts, during the debriefing interviews, and with patients during the main course of the research.

Special attention was paid to the issue raised by Speight (2009), which was discussed in Chapter 8, about any difficulty involved in answering to the hypothetical situation of diabetes absence. The answers were unanimous that this did not present any problem, because they all had life without diabetes in the past that they could compare with their present condition. They could also compare their lives with people without diabetes in their immediate environment. The results are considered satisfactory and no problem arose during the interviews during the main course of this research.

11.4 Conclusion

This study is the first to translate and validate a diabetes-specific QoL measure in Greek. The results of the internal consistency assessment indicate a very good reliability of the ADDQoL-Gr. for the Greek population.

The results concerning the validity of the ADDQoL-Gr indicate that the instrument is valid in measuring what it purports to measure, that is the QoL of people with diabetes in Greece. The validity analysis showed that the ADDQoL-Gr compared with the generic SF-36 provides a more targeted measure of QoL.

The type of the statistical analysis did not permit the assessment of the ADDQoL-Gr responsiveness as it requires a longitudinal study. This property has never been assessed in any of the ADDQoL versions. However, this is a topic of great interest for future research that is planned to take place after the completion of the present thesis. The economic-financial-social crisis that emerged in Greece during the last two years is a strong motive for re-examination of the QoL among people with diabetes in Greece, as well as a good opportunity to assess the responsiveness of the new instrument.

Internal consistency and validity of the ADDQoL-Gr were demonstrated with satisfactory results leading to the conclusion that overall this measure should be considered as a very good instrument. The very good psychometric properties make ADDQoL-Gr suitable for use by health professionals, planners, and interest groups.

The instrument is now accepted by the original developer and the MAPI institute as the Greek version of the ADDQoL and it is available for use by anyone interested in the field. According to the 3rd March 2008 Agreement (Appendix D) copyright in this questionnaire is owned by Prof Clare Bradley of Royal Holloway University of London, Egham, Surrey TW20 0EX, England.

PART V: Diabetes and Quality of Life in Greece

Chapter 12: The impact of Diabetes on QoL

12.1 Introduction

It is well established in international literature (chapter 5) that Quality of Life is impaired by diabetes. This chapter examines the impact diabetes has on diabetes patients in Greece using the ADDQoL-Gr.

To this end the chapter has been subdivided into three headings:

- the general impact that the disease has on Greek diabetes population;
- the impact that diabetes has on various life domains, and;
- the relationship of QoL with various demographic, socioeconomic, and medical characteristics of the patients.

12.2 Method

The available data contain the variables included in the medical-demographic, the SF-36 and ADDQoL-Gr questionnaires. Quality of life (ADDQoL-Gr), health status (SF-36) indices and the two global questions of ADDQoL-Gr are viewed as response (dependent) variables, whereas the remaining variables containing medical, demographic, and socioeconomic status are regarded as predictors (independent variables).

Descriptive statistics for central tendency (mean, median) and variability (standard deviation, minimum and maximum) were used to present continuous variables while categorical variables were expressed as frequencies and percentages. Each variable was first examined at a univariate level (mean, standard deviation, median, minimum and maximum values). Normality of the distribution was checked with Kolmogorov-Smirnov test. Theory suggests that when distribution is not normal non-parametric tests are used. It also suggests that when samples are large parametric methods can also be used to analyse these data. However, when outcomes are ordinal, ranked, or subject to outliers analyses with parametric methods are difficult, because major

assumptions are needed about their distributions and the tests involve estimation of the key parameters of that distribution. If the test deviate strongly from these assumptions nonparametric tests are preferred because they do not rely on assumptions about distribution. Therefore there is a trade-off between the power of the test, that the parametric methods provide, and the possibility of obtaining invalid results and reach incorrect conclusions, if the distribution assumption is strongly violated. In that case nonparametric tests are preferred. Normality was checked and the result of the Kolmogorov-Smirnov test showed a non-normal distribution. To avoid the danger of reaching incorrect conclusions it was decided that non parametric methods should be used, such as Spearman's correlation and Kruskal Wallis test.

Some variables, like monthly salary, educational level, the HbA_{1c} levels and the annually expenses, were treated as ordered categories variables rather than categorical variables in order to assist a meaningful interpretation of results. Mann-Whitney U tests were used to identify any significant differences in ADDQoL scores between patients dichotomized on the basis of diabetes type, gender, presence of complications, hospitalization, and participation in any diabetes club or association.

The association between the average weighted ADDQoL scores and the demographic characteristics with more than two categories was assessed with Kruskal-Wallis test. This was followed by post hoc tests in order to identify exactly in which categories there was the difference. For this purpose Mann-Whitney U test was used for all possible group comparisons with Bonferroni adjustment. Kruskal-Wallis test was also used to explore differences in the average weighted ADDQoL scores among the various testing sites (hospitals), the type of therapy, the frequency of visits to the doctor and the consultants of various specialties.

Spearman's rank correlation coefficient (ρ) tested the association between ADDQoL scores and the Global Questions of ADDQoL, the monthly salary, the HbA_{1c} levels and the expenses about diabetes. Cohen's conventions were used to interpret the results: any correlation greater than 0.5 is large, 0.3-0.5 is moderate, 0.1-0.29 is small, and anything smaller than 0.1 is insubstantial.

Missing data were handled by pairwise deletion that is only the specific missing values were removed from the analysis and not the entire questionnaire that contained missing values. All tests were two tailed and statistical significance was considered for P values of less than 0.05. Statistical analyses were performed using the Statistical Package for the Social Sciences 19 (SPSS-19).

12.2.1 Scoring

In order to score and calculate the mean weighted score of the ADDQoL-Gr, User Guidelines in combination with the Supplement ADDQoL 19. (rev. 20.6.06) were used. (Unpublished-Personal communication with the developer Professor Bradley). There are 2 global questions and 19 questions on specific life domains, scored on a 5 point scale followed by a 4 point importance rating scale.

12.2.1.1 Overview Items of the ADDQoL-Gr

For the first overview item the possible answers extended from “excellent” to “extremely bad”. The scores assigned to each one of the possible answers were from 3 (“excellent”) to -3 (“extremely bad”). Similarly for the second overview item the possible answers extended from “very much better” to “very much worse”. The scores assigned to each one of the possible answers were from -3 (“very much better”) to +3 (“very much worse”).

12.2.1.2 The 19 specific items

The impact of diabetes on applicable domains (part ‘a’ of an item) were rated on a scale of -3 (maximum negative impact) to +1 (maximum positive impact). The rate of the importance of those domains for patient’s QoL (part ‘b’ of an item) was scored on a scale from 3 (very important) to 0 (not at all important).

Weighted-impact score for each domain is obtained by multiplying the impact ratings by the corresponding importance rating to provide a score ranging from -9 (maximum negative impact) to +3 (maximum positive impact).

An average weighted impact score was derived by summing the applicable item weighted impact scores and divided by the number of applicable domains. This is the overall Average Weighted Impact (AWI) score.

Selected domains have a “not applicable (N/A) option. N/A responses were excluded from the scoring for that individual as these items are not applicable to the individual.

12.3 Results

12.3.1 Impact of Diabetes on Quality of Life

12.3.1.1 General Impact Score

The mean AWI score was -2.62 ± 1.81 (range: -8.83 to 0.26), indicating a negative impact of diabetes on quality of life in the patients participating in the study (Table 15). This result was expected and it is in complete agreement with all previous studies concerning diabetes and QoL. Also, it should be noted that the vast majority of respondents scored their diabetes-dependent QoL negatively, despite the fact that they considered their present QoL in general in positive terms as “good”.

Only 4 out of the 1028 participants reported a positive effect of diabetes on their quality of life. Although the number is not significant it was an unexpected finding, corroborating Professor Bradley’s views on the possibility of a positive diabetes effect. The probability of such a positive effect was doubted during the initial stages of the research (see 8.5.1: the advantages of ADDQoL).

12.3.1.2 Overview items and mean weighted ADDQoL-Gr scores

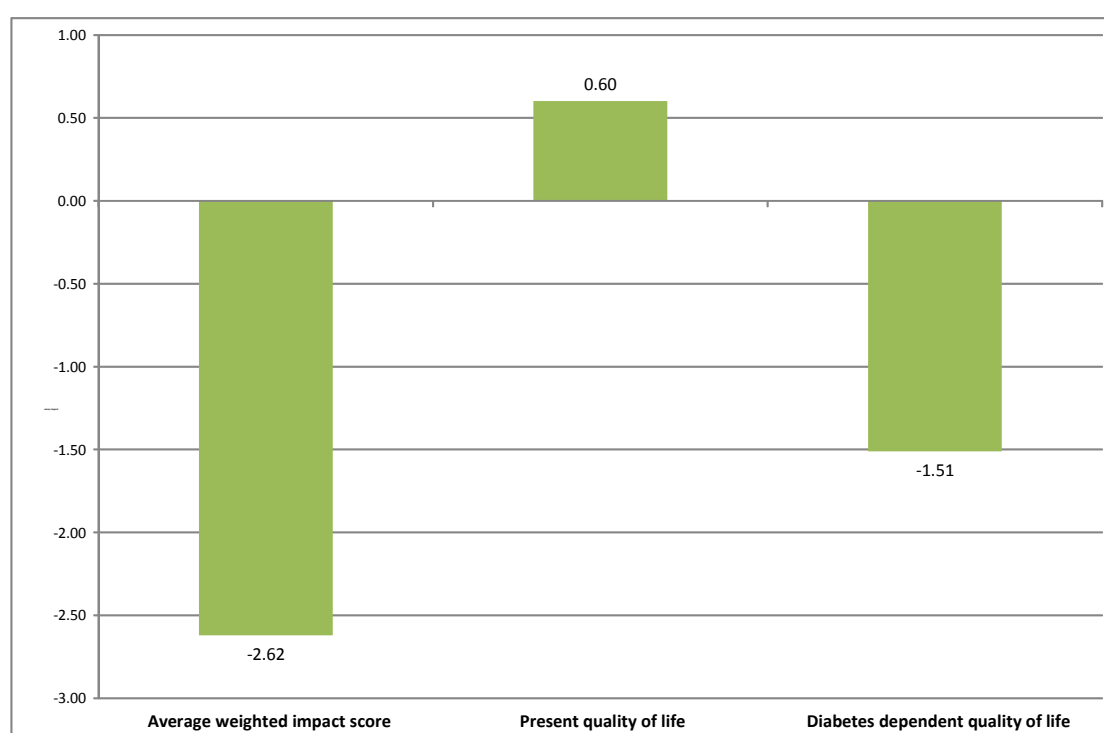
Overview item 1 found that the patients considered their present quality of life was “good” with a positive mean values of 0.60. When the patients were asked whether their QoL would improve without diabetes they felt that diabetes had a negative

impact on their QoL with a mean score of -1.51 ± 0.96 and believed that their QoL would be much better without diabetes (Table 15, Figure 4).

Table 15: Descriptive statistics for ADDQoL total and overview items

	Mean	SD	n
Average Weighted Impact	-2.62	1.81	1027
Present QoL	0.60	1.02	1027
Diabetes Dependent QoL	-1.51	0.96	1027

Figure 4: Overview items in comparison to the average weighted impact score.



12.3.1.3 Impact of diabetes on life domains

12.3.1.3.1 Distribution of Responses

Distribution of responses to ADDQoL items is shown in table 16. Thus, items have been classified according to: a) their impact on QoL, b) to their importance and c) their weighted impact scores. Weighting impact scores by importance ratings changes the ranking of domain mean scores for the impact of diabetes apparent with unweighted scores. In specific, although people's freedom to eat receives the highest means for both unweighted and weighted impact, rankings of other items are particularly altered by weighting.

Diabetes has the greatest impact on "freedom to eat" (mean±SD: -1.75±1.04) and least impact on "people's reaction" to diabetes (mean±SD: -0.56±0.89). "Family life" was rated as the most important (mean±SD: 2.66±0.51) and "freedom to drink" was rated as the least important (mean±SD: 1.46±1.05) ADDQoL domain. After weighting was considered the most negative impact of diabetes was still freedom to eat (mean±SD: -4.38±3.17). The frequency of utilization of NA options ranged from 4.2% (family life) to 61.5% (work).

Table 16: Distribution of responses *

Domain	Not Applicable responses		Impact rating		Importance rating		AWI scores	
		(% of responses)	mean	SD	mean	SD	mean	SD
Leisure Act.			-1.09	0.96	2.08	0.61	-2.35	2.41
Work	632	(61.5)	-1.19	1.02	2.58	0.58	-3.09	2.86
Journeys			-1.16	1.00	2.07	0.76	-2.52	2.55
Holiday	243	(23.7)	-1.24	0.98	2.35	0.65	-2.98	2.69
Phys. health			-1.25	1.01	2.27	0.59	-2.96	2.73
Family life	43	(4.2)	-1.13	1.01	2.66	0.51	-3.06	2.89
Social life			-0.82	1.02	2.42	0.61	-2.04	2.73
Close personal relationship	200	(19.5)	-0.99	1.06	2.52	0.57	-2.53	2.96
Sex life	375	(36.5)	-1.10	1.06	2.49	0.60	-2.82	2.96
Physical appearance			-0.78	1.00	2.10	0.69	-1.77	2.47
Self-confidence			-1.08	0.99	2.30	0.58	-2.62	2.75
Motivation			-1.04	1.05	2.32	0.58	-2.52	2.86
People's reaction			-0.56	0.89	2.09	0.69	-1.28	2.22
Feelings about the future			-1.30	1.04	2.32	0.63	-3.25	2.96
Financial situation			-0.89	1.00	2.38	0.62	-2.30	2.80
Living condition			-1.03	1.05	2.37	0.57	-2.60	2.89
Dependence on others			-1.05	1.05	2.43	0.65	-2.66	2.94
Freedom to eat			-1.75	1.04	2.24	0.82	-4.38	3.17
Freedom to drink			-1.06	1.05	1.46	1.05	-2.29	2.81

*n=1027

Table 17 shows the effect of weighting on impact ratings. Weighting impact scores by importance changes the ranking of most domains. However, freedom to eat and feelings about the future remain first and second respectively for both unweighted and weighted impact. Also, impact on friendship and social life, physical appearance, and people's reaction does not change with weighting. Other domains are highly influenced by weighting. Journeys, work, drinking, dependence on others, and personal relationship are some of the altered domains. It is worth noting that the ranking of the two with the highest impact and the last three with the lowest one is not altered by weighting. This could imply that these domains are important to almost all of respondents. On the other hand, the change in ranking observed with weighting

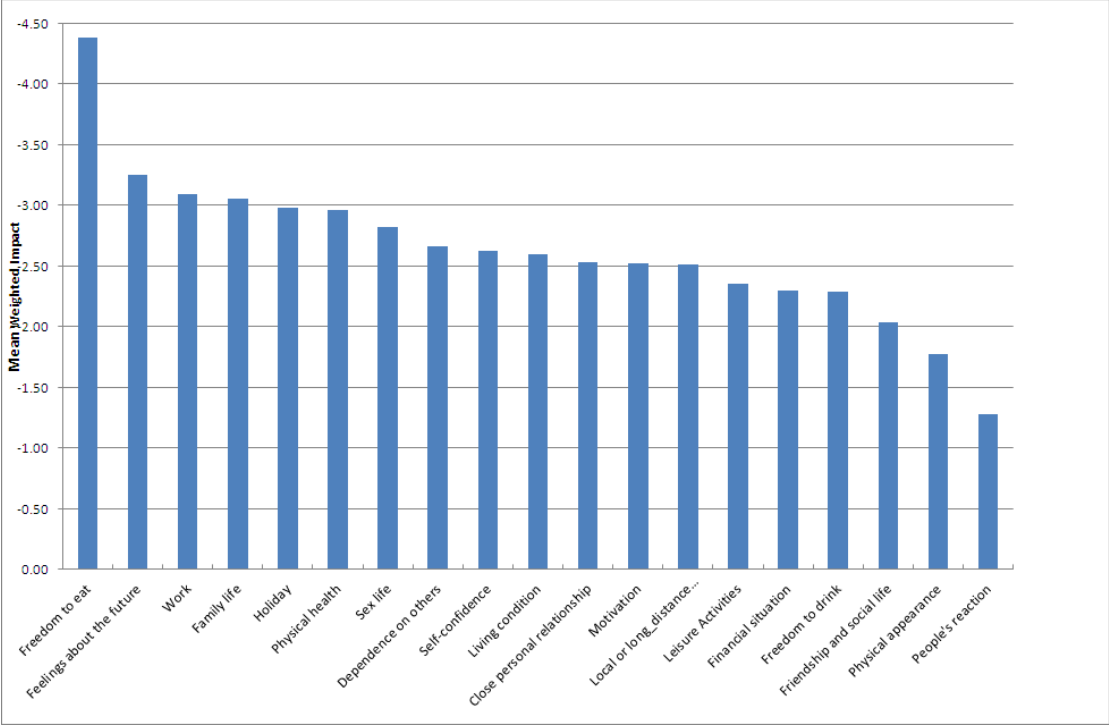
shows that although respondents believe that these five domains have an impact on their lives, these domains have importance only to some of them.

Table 17: Differences in ranking between unweighted – weighted means

Domain	Ranks of unweighted means	Ranks of weighted means
Freedom to eat	1	1
Feelings about the future	2	2
Physical health	3	6
Holiday	4	5
Work	5	3
Local or long-distance journeys	6	13
Family life	7	4
Sex life	8	7
Leisure Activities	9	14
Self-confidence	10	9
Freedom to drink	11	16
Dependence on others	12	8
Motivation	13	12
Living condition	14	10
Close personal relationship	15	11
Financial situation	16	15
Friendship and social life	17	17
Physical appearance	18	18
People's reaction	19	19

Figure 5 shows the impact of diabetes on individual life domain, indicating that the most negative impact of diabetes occurs to “freedom to eat” and the least negative impact on “people’s reaction”.

Figure 5: Impact of diabetes on individual life domains (mean weighted ADDQoL score)



12.3.1.3.2 Impact of diabetes on individual life domains (by gender)

Diabetes affects both male and female patients in all domains of life (Table 18). However, the impact differs between genders and among the 19 life domains and in some cases the difference is significant.

Table 18: Impact of diabetes on individual life domains (by gender)

Table 16. Impact of diabetes on individual life domains (by gender)

Domain	Male		Females		P value
	AWI scores		AWI scores		
	mean	SD	mean	SD	
Leisure Activities	-2.40	2.50	-2.32	2.35	0.8638
Work	-2.98	2.82	-3.24	2.90	0.4596
Local or long journeys	-2.50	2.689	-2.53	2.46	0.4119
Holiday	-2.85	2.60	-3.07	2.76	0.3740
Physical health	-2.95	2.81	-2.97	2.68	0.6572
Family life	-3.11	2.88	-3.02	2.89	0.5481
Friendship and social life	-2.35	2.89	-1.83	2.59	0.0040*
Close personal relationship	-2.90	3.11	-2.22	2.79	0.0007*
Sex life	-3.57	3.08	-2.00	2.61	<0.0001*
Physical appearance	-1.52	2.34	-1.95	2.53	0.0054*
Self-confidence	-2.78	2.94	-2.51	2.60	0.2762
Motivation	-2.65	3.01	-2.43	2.74	0.5318
People's reaction	-1.40	2.31	-1.20	2.15	0.1008
Feelings about the future	-3.21	3.04	-3.28	2.90	0.4875
Financial situation	-2.35	2.90	-2.26	2.72	0.9104
Living condition	-2.68	2.94	-2.55	2.86	0.4342
Dependence on others	-2.76	3.00	-2.60	2.88	0.4583
Freedom to eat	-4.39	3.25	-4.38	3.11	0.8710
Freedom to drink	-2.80	3.06	-1.94	2.56	<0.0001*

*indicates statistical significance

12.3.1.3.3 Impact of diabetes on individual life domains (by type of diabetes)

There are some statistically important differences of the weighted impact of diabetes on individual life domains between the type I and type II diabetes patients (Table 19).

Table 19: Impact of diabetes on individual life domains (by diabetes type)

Domain	Diabetes Type I AWI scores		Diabetes Type II AWI scores		P value
	mean	SD	mean	SD	
Leisure Activities	-2.22	2.46	-2.40	2.38	0.1334
Work	-2.91	2.66	-3.33	3.08	0.2347
Local or long journeys	-2.36	2.54	-2.58	2.55	0.1760
Holiday	-3.15	2.88	-2.90	2.58	0.5903
Physical health	-3.05	2.99	-2.93	2.62	0.9459
Family life	-2.74	2.94	-3.19	2.86	0.0134*
Friendship and social life	-1.67	2.70	-2.18	2.72	0.0008*
Close personal relationship	-2.42	3.07	-2.59	2.91	0.2647
Sex life	-2.35	2.92	-3.15	2.96	0.0001*
Physical appearance	-1.45	2.54	-1.89	2.42	0.0002*
Self-confidence	-2.71	3.00	-2.59	2.65	0.7337
Motivation	-2.12	3.09	-2.68	2.74	0.0003*
People's reaction	-1.26	2.38	-1.29	2.16	0.4733
Feelings about the future	-3.12	3.10	-3.30	2.90	0.2409
Financial situation	-2.07	2.72	-2.37	2.82	0.1448
Living condition	-2.59	3.02	-2.61	2.84	0.6372
Dependence on others	-2.68	2.90	-2.66	2.95	0.6373
Freedom to eat	-3.32	3.20	-4.80	3.05	<0.0001*
Freedom to drink	-2.30	2.82	-2.29	2.80	0.9682

*indicates statistical significance

12.3.1.4 Discussion

“Freedom to eat” receives the highest means both for weighted and unweighted impact, indicating that the greatest negative impact of diabetes is observed for this domain. The impact of this item is even higher for people with Type 2 diabetes. The heavy impact was expected taking into consideration previous studies in Europe and Asia (Bradley and Speight, 2002; DAFNE study group, 2002; Wee *et al.* 2006; Costa *et al.* 2006).

“People’s reaction” has the lowest means in both rankings. This could be an indication that diabetes does not stigmatise people in Greece any more. These results are in agreement with the original ADDQoL and could be considered as an indication that the psychometric properties of the instrument are retained.

The fact that the ADDQoL measures QoL according only to domains applicable to the patient is probably the major advantage of the instrument. However, the non-applicable option might lead to situations where strong biases emerge and change the results of the analysis. To confront this problem the missing items of the non-applicable domains should be isolated and removed from the analysis (weighting).

When weighting takes place the ranking of domain mean scores changes in most of the remaining items. This is because all non-applicable domains are not scored. Thus, “work” moves from rank 5 (unweighted) to rank 3 (weighted). “Local or long-distance” journeys moves from rank 6 (unweighted) to rank 13 (weighted). “Family life” moves from rank 7 (unweighted) to rank 4 (weighted). Rankings of other items are altered to some extent by weighting.

Some important statistically significant differences are observed between genders when the impact of diabetes on the ADDQoL domains is assessed. For men, the impact of diabetes is higher than women on friendship and social life, close personal relationship, sex life, and freedom to drink domains, while women report more impact on physical appearance.

Diabetes in type II patients has a greater impact, compared with type I patients, on “family life”, “friendship”, “social life”, “sex life”, “physical appearance”, “motivation”, and “freedom to eat”. The first four and to some extent “physical appearance” and “motivation” could be attributed to the higher age of the type II patients. The lower impact on “freedom to eat” for type I patients, compared with type II, could be explained by the use of insulin from type I patients.

Chapter 13: Diabetes-related QoL determinants

13.1 Diabetes Dependent QoL in relation to Demographic and Medical Characteristics

13.1.1 QoL and Type of Diabetes

Mann-Whitney U test showed that there was a statistically significant difference in the mean weighted ADDQoL score between the two different types of diabetes (Table 20). Patients with type 2 diabetes had significantly lower mean ADDQoL score, indicating more negative impact of diabetes ($p < 0.05$).

Table 20: ADDQoL scores by type of diabetes

Diabetes Type	Mean	S.D	n	p value
Type 1	-2.460	1.871	281	0.019*
Type 2	-2.686	1.789	743	

In literature, the relationship between diabetes type and QoL is inconclusive and sometimes contradictory (Mayou et al, 1990; Jacobson *et al.* 1994; Stewart *et al.* 1994). Jacobson *et al.* (1994) found that type 2 patients enjoyed a higher level of QoL than type 1, even those treated with insulin. My findings contradict Jacobson's results, thus it needs further investigation. First, the type of instruments used played an important role in assessing QoL. Jacobson *et al.* used a generic instrument (the SF-36) and a near-generic instrument (the DQOL), created for Type 1 diabetes only. The explanation for the near-generic nature of the DQOL can be found in Appendix B. It is not certain that these instruments can give accurate results for such a sensitive issue. My findings using the SF-36 do not give a clear picture on the issue (Chapter 14).

Second, type of diabetes *per se* should be associated with QoL as long as it is examined in relation to confounding factors such as age or treatment regimen. According to Woodcock *et al.* (2001) the relation of Type 2 diabetes with QoL is intriguing because the disease is to a large extent asymptomatic for many years, making people suffer more from the treatment than from the disease itself. Diet, which is an essential part of the Type 2 treatment, imposes more severe restrictions on people with Type 2 diabetes. This, combined with the ADDQoL results that show “freedom to eat” as having the greatest impact on QoL, might be an adequate explanation for this finding.

Further analysis shows that if we take age into account, diabetes type does not influence the ADDQoL score (see 13.1.3).

13.1.2 Diabetes Dependent QoL and Gender

Respondents were classified according to gender: Males: n= 420 (40.9%), females: n=605 (58.9%). There were 2 respondents with missing data (0.2%). In this case there was no statistically significant difference ($p>0.05$) between two genders regarding mean weighted AQQDoL score (Table 21).

Table 21: ADDQoL scores by gender

Gender	Mean	S.D.	n	p value
Male	-2.745	1.968	420	0.277
Female	-2.536	1.697	605	

Male diabetes patients in general report higher levels of QoL, as well as higher health, status than female ones (Glasgow *et al.* 1997; Verbrugge, 1982; Kind *et al.* 1998; Michalos, 2000; Rubin, 2000; Eiser *et al.* 1992; Redekop *et al.*, 2002; Unden *et al.*, 2008). Nevertheless, in this case men appear to have a lower QoL level than women. The difference is not statistically significant, but still does not agree with the main trend. It should be noted that the SF-36 results from this study show that men reported a higher level of health status.

Although the statistical difference is not significant still there should be an explanation why the results deviate from the main stereotype, which clearly suggests that men report higher levels of patient reported outcomes. The reason why this study differs from others is uncertain and three different possible explanations could be given, each one standing in its own capacity or could be a combination of all three.

The first one could be that men seem to be more troubled by the limitations on personal freedom caused by diabetes. This view first expressed by Gafvels (1993) might be supported by examining the different effects that could be seen on table 18 of diabetes impact on individual life domains, where men suffer more on domains such as friendship and social life, close personal relationship, sex life, and freedom to drink domains, while women suffer significantly more only on physical appearance.

The second answer might be that men in Greece are now emancipated from the stereotype of being tougher than women and it is nowadays more socially acceptable to report their feelings, depression or anxiety, which according to some (female) writers was something permissible and more acceptable in the near past, even in western societies, only to women (Nathanson, 1975; Bradley, 1980). Thus, the views expressed in the past that women are more sensitive and express their emotions more overtly than men may no longer be valid in contemporary Greece.

The third answer, and possibly the most convincing one, is the presence of a confounding factor such as age. The relation or interaction of gender, age groups and type of diabetes, is examined more thoroughly at the next stage of analysis, and age seems to play an important role.

13.1.3 Diabetes Dependent QoL and Age

According to the literature older individuals report lower QoL (Lloyd and Orchard 1999; Rubin, 2000). Although this statement seems to be generally correct, this approach could be considered as an oversimplification, because age and QoL have a more complicated relation, especially when other factors such as type of diabetes or gender are concerned.

13.1.3.1 QoL & Age

To examine this relationship the Kruskal-Wallis test was used in order to compare the mean difference of ADDQoL score between different age groups. Also, in order to assess how the ADDQoL score of various age groups was affected when the gender and the type of diabetes were taken into consideration, a factorial ANOVA was performed.

Table 22 shows the ADDQoL scores by age groups. There was a statistical significant difference between the mean ADDQoL score and the different age groups ($p=0.001$). In particular, younger patients (<31 years old) differed significantly from all other age groups, meaning that for younger patients diabetes had significantly less impact compared with older patients.

Table 22: ADDQoL scores by age group

Age Groups (in years)	Mean	Std	n
<31	-1.90	1.45	84
31-40	-2.44	1.84	104
41-50	-2.99	2.22	90
51-60	-2.92	2.06	200
61-70	-2.57	1.75	292
71-80	-2.58	1.52	211
≥ 81	-2.71	1.48	36

Patients <31 years of age and 31-40 assessed their QoL higher than the older ones, probably because have shorter duration of diabetes, fewer complications, better social life and physical condition.

It seems that ADDQoL score is decreasing with age up to the age of 50-60. There was a slight increase in the ADDQoL score, for the age groups of 61-70 years and 71-80 years compared with the 41-60 age groups. This, at first sight seems to be a paradox. However, three factors should be taken into consideration:

- First, it should be noted that there are theories suggesting that well-being and happiness may improve with age (Lawton 1996; Mroczek and Kolarz, 1998; Bowling, 2005e). This could be explained by the fact that the age group 61-70 includes people who are newly retired, changing therefore their way of life and loosing the distress that accompanies work and family problems. They have time, freedom and independence to enjoy life (Bowling, 2005e).
- Second, as the duration of the condition increases patients come to terms with their diabetes and the conditions imposed by it. The so-called response shift phenomenon has been analysed in chapter 3 and it involves changing of individuals' internal standards, values and conceptualization of life (Sprangers and Schwartz, 1999).
- Third, Trief *et al.* (2003) argued that older people (the group 71-80 years of age), have coping skills, social relationships or other factors may act as buffers and prevent high levels of distress, although they face functional problems. The fall in QoL apparent after the age of 80 years could be a result of rapid deterioration in physical health.

13.1.3.2 QoL Age and Gender

There was a significant main effect of the age category on the ADDQoL score. The F- ratio was highly significant $F(6, 1001) = 4.17, p < 0.0001$. Age significantly affected ADDQoL score, when we ignored gender. The Games-Howell post hoc test

revealed that the ADDQoL score was significantly high in younger patients (<31 years old) than all the other age groups combined. There was a non-significant main effect of gender on the ADDQoL score $F(1, 1001) = 0.005$, $p = 0.946$. This means that if we ignore age, gender did not influence ADDQoL score. There was a significant interaction effect between the age and the gender on the ADDQoL score, $F(6, 1001) = 2.41$, $p = 0.026$.

This indicates that the two genders were affected differently by age. Male patients less than 31 years of age and over 81 years old had significantly higher ADDQoL score compared with female patients, indicating a better quality of life. Regarding the rest of the age groups (from 31-80 years old) female patients had higher (less negative) ADDQoL scores compared with men. For both genders ADDQoL score dropped after the age of 31 years old and started to increase after the age of 61 years old. However, for female patients after 70 years old the ADDQoL score started to decrease again, while for male patients of the respective age the ADDQoL score continued to increase, indicating an improvement in quality of life (Table 23).

Table 23: ADDQoL scores by age group and gender.

Age Groups	Male		Female	
	mean	SD	mean	SD
≤31	-1.50	1.23	-2.27	1.56
31-40	-2.57	1.95	-2.36	1.78
41-50	-3.35	2.63	-2.78	1.93
51-60	-3.36	2.25	-2.59	1.84
61-70	-2.73	1.88	-2.46	1.66
71-80	-2.63	1.45	-2.55	1.57
≥81	-2.30	1.56	-2.94	1.42

13.1.3.3 QoL Age and Type of Diabetes

There was a significant main effect of age on the ADDQoL score. The F- ratio was highly significant $F(6, 1001) = 4.16$ $p < 0.0001$. Age significantly affected ADDQoL score, when type of diabetes was ignored. On the contrary, there was a non-significant main effect of diabetes type on the ADDQoL score $F(1, 1001) = 0.74$, $p = 0.786$. This means that if we ignore age, type of diabetes does not influence ADDQoL score.

However, there was a significant interaction effect between age and the type of diabetes on the ADDQoL score, $F(5, 1001) = 3.11$, $p = 0.009$. This indicates the effect of age on ADDQoL score was different for diabetes type I patients than it was for type II patients. In specific patients with Type 1 diabetes less than 40 years old had significantly higher ADDQoL score compared with diabetes Type 2 patients. For patients with type I diabetes ADDQoL score decreased with age, at least up to 60 years old, where it started to increase (Table 24). On the contrary for patients with Type 2 diabetes ADDQoL score increased with age and after the age of 61 it started to have a slight decrease. At the age group of 61-70 patients between the two types of diabetes differ significantly regarding ADDQoL score, with Type 2 diabetes patients having higher ADDQoL score (-2.52 ± 1.74).

Table 24: ADDQoL scores by age group, gender, and type of diabetes.

Age Groups	Type I		Type II	
	mean	SD	mean	SD
Gender				
≤31 years	-1.90	1.45	-	-
31-40	-2.28	1.77	-4.11	1.91
41-50	-2.89	1.98	-3.12	2.48
51-60	-3.26	2.39	-2.87	1.98
61-70	-3.68	1.79	-2.52	1.74
71-80	-2.39	2.29	-2.59	1.51
≥81 years	-2.80	.	-2.70	1.50
Male	-2.51	2.03	-2.84	1.93
Female	-2.43	1.74	-2.58	1.68

Regarding the effect of gender on ADDQoL score between the different types of diabetes, there was no significant different effect. There was a non-significant main effect of gender on the ADDQoL score $F(1, 1018) = 1.74$, $p = 0.188$ and of type of diabetes $F(1, 1018) = 3.58$, $p = 0.059$. This means that if we ignore type of diabetes, gender does not influence ADDQoL score and also if we ignore gender, type of diabetes does not influence ADDQoL score. There was no significant interaction effect between the type of diabetes and the gender on the ADDQoL score, $F(6, 1018) = 0.516$, $p = 0.473$. This indicates that Type 1 and Type 2 diabetes patients were not affected differently by gender.

13.1.4 QoL and Complications

According to literature diabetes complications is a strong predictor for QoL. According to Rubin and Peyrot (1999) complications are the most important disease-specific determinant of QoL. People with complications in general report a lower level of QoL compared with people without complications (Lloyd et al 1992; Klein *et al.*, 1998; Trief *et al.*, 1998; de Visser *et al.*, 2002; Maddigan *et al.*, 2005). This is because complications affect many aspects of patient's life, patient's views of diabetes, social life and self-perception (Gafvels et al. 1993).

In the questionnaire the question on complications included answers for visual impairment, myocardial infarction, nephropathy, amputation, erectile dysfunction, and "other". 303 (29.5%) of the total sample of 1027 reported at least one diabetes complication; 55 of them reported two complications.

As expected, patients who experienced diabetes complications had significantly lower ADDQoL average weighted impact scores, compared with those who didn't have any complication (Table 25).

Table 25: ADDQoL scores with and without complication

Complications	n (%)	Mean	SD	p value
Yes	303 (29.5%)	-3.364	2.023	<0.0001*
No	717 (69.8%)	-2.306	1.623	
missing	7 (0%)			

* indicates statistically significant difference

The most frequent complication was visual impairment, something that could not easily be verified, as it was impossible to confirm to what extent the damage to eyesight was caused by diabetes or any confounding factor such as age (Table 26). Erectile dysfunction and nephropathy seem to have the most serious impact on QoL (-4.71 and -4.23 respectively with a mean weighted average of -2.65 for the total sample).

Some of the above results might be presumed as expected, in the sense that it is already well established that complications are the most decisive predictor for the quality of life of people with diabetes.

However, this table shows that microvascular complications have a greater impact than the macrovascular disease of myocardial infarction. This contradicts the long standing view in international literature that macrovascular complications, especially coronary heart disease (CHD), have the most negative impact on QoL, followed by non-vascular diseases (Lloyd *et al.*; Wandell *et al.* 1998; Hart *et al.* 2003; Wandell, 2005). Hart *et al.* (2003), using two generic measures, reported that microvascular complications such as neuropathy, retinopathy and/or nephropathy did not have any statistically significant influence on QoL.

The most astonishing result is that among all complications, and consequently among all determinants of diabetes-related QoL, erectile dysfunction (ED) had the most negative impact on QoL. This finding is, to the best of our knowledge, unique in international literature. We are unaware of a study concerning the weighted impact of each complication, including ED, on diabetes-related QoL.

Erectile dysfunction among all complications appears to be the most understudied one in relation with QoL, despite its substantial prevalence among the male diabetes population (De Berardis *et al.*, 2002). Estimations of ED prevalence among male diabetes patients vary from 26% to 71% with type of diabetes, age, duration and co morbidity (e.g. hypertension) to be the most significant confounding factors for these variations. The definition of ED was also responsible for the variations observed in prevalence (Siu *et al.*, 2001; Bacon *et al.*, 2002; De Berardis *et al.*, 2002; Fedele *et al.* 2000; Giuliano *et al.*, 2004; Grover *et al.*, 2006).

There are not any studies investigating the relative impact ED has on QoL. There are only three studies reporting the impact of ED either on QoL in general, that is not in relation with other complications, or in comparison with healthy controls, or even with diabetes-patients without ED. De Berardis *et al.* (2005) in a longitudinal study, using a generic measure the SF-36, reported that ED caused a negative impact on QoL and that this impact was deteriorating during the three years of the study. Penson *et al.* (2003) exploring data bases regarding erectile dysfunction concluded that men with diabetes and ED respond worse quality of life than men with ED but without

diabetes. Avasthi *et al* (2011) found that men with diabetes and ED had poorer QoL in all domains compared with men with diabetes but without ED.

Therefore, the problem of ED, as a major predictor of QoL, should be investigated further, as it constitutes a major problem for diabetes population.

Table 26: ADDQoL scores by complication, number and severity of complications

Complication	n=303 (% of n)	% of total n=1027	Mean score	SD
Visual Impairment	173 (57.1%)	16.84%	-3.36	1.98
Myocardial Infarction	39 (12.9%)	3.80%	-3.63	2.04
Nephropathy	35 (11.6%)	3.41%	-4.23	2.07
Amputation	9 (3.0%)	0.88%	-3.94	2.26
Erectile dysfunction	29 (9.6%)	2.82%	-4.71	2.56
Other	73 (24.1%)	7.11%	3.16	1.90
Over 2 complications	55 (18.6%)	5.36%	-4.60	2.05
Complication severity				
Slight	120 (39.6)	11.68%	-3.07	1.983
Medium	121(39.9)	11.78%	-3.28	1.950
Severe	57 (18.81)	5.55%	-4.11	2.118

Another point of great importance on the issue of complications is the impact that their number has on QoL. Patients who reported more than one complication score very low on QoL. The mean score -4.601 compared with the mean of -2.306 for patients without complications shows the gravity of the condition and the importance this issue has for the QoL determination.

13.1.5 QoL and severity of complications

Having examined the role of complications in general and the influence that each one has on the level of QoL, the role of severity was assessed. There was a statistically significant difference between the ADDQoL score and the severity of the complications ($p=0.004$). Patients with higher severity had statistically significant lower ADDQoL score. Thus, people with severe complications appear to have an average weighted impact score of -4.11, well below the mean score of -2.62 of the general Greek population with diabetes (Table 26).

Another point worth mentioning is that the ADDQoL-Gr was proved to be sensitive enough and capable of detecting the changes that the degree of complications' severity has on the level of QoL.

13.1.6 QoL and Treatment Regimen

Treatment of diabetes from the QoL perspective is an interesting factor because diabetes, in its initial stages, is completely asymptomatic and does not impose a burden on an individual's QoL; the main burden is caused by the treatment (Woodcock *et al.*, 2001).

Table 27: ADDQoL scores by treatment regimen

Therapy	Mean	SD	n	p value
Insulin	-2.78	1.90	533	0.034*
Oral medication	-2.44	1.68	461	
Diet only	-2.57	1.94	31	

Consistent with previous research (Welch *et al.* 2003), as well as our expectations people treated with insulin reported significantly greater impact of diabetes (-2.78). However, the interesting point here is the fact that people being on diet only have more negative score compared with people treated with oral agents (Table 27). An explanation for this finding, which at first sight seems to be a paradox, might be the view expressed by physicians when this issue was raised, that people on “diet only” struggle harder than people who think that medication will manage their diabetes for them.

13.1.7 QoL and Glycaemic control

A degree of confusion can be observed in the literature concerning the relationship between good glycaemic control and QoL. This relationship is a complicated issue and a topic of major dispute. Snoek (2000) argued that there is a relatively weak

association between patient's objective health status and their subjective QoL. Describing the inconsistent association between the two he argues that there are four categories of patients: people who experience high QoL with good glycaemic control; those with good QoL with poor glycaemic control; Individuals with a low level of QoL despite the good glycaemic control; and people with low QoL and poor glycaemic control.

Nevertheless, high levels of HbA_{1c} lead to serious diabetes complications such as neuropathy, retinopathy, microvascular complications, or nephropathy (DCCT, 1996; UKPDS, 1998a; UKPDS, 1999). The UKPDS (2009) argued that different treatments do not affect QoL. Other studies, although they accept the relationship between HbA_{1c} and microvascular complications, dispute the relationship between glycaemic control and macrovascular complications (ACCORD, 2008; ADVANCE, 2008; Duckworth *et al.* 2009).

However, a number of writers suggest that there is an association between intensive glycaemic control and QoL. (Ishii *et al.* 2008; Testa and Simonson, 1998; Klein *et al.*, 1998; Lloyd and Orchard 1999; Goddgin *et al.*, 1999; Kamarul *et al.* 2010; Imayama *et al.* 2011). Others argue that there is little or no relationship between HbA_{1c} and self-reported outcomes (Weinberger *et al.* 1994; Wredling *et al.* 1995; Aalto *et al.* 1997; Sonnaville *et al.* 1998).

The reason why investigators express diametrically different views might lie on the type of investigations and the instruments used. The last seems to play an important role in examining the relationship between glycaemic control and QoL. Rubin and Peyrot focus on the type of instrument arguing that a number of studies suggest that this relationship exists, especially when QoL is assessed by a diabetes-specific measure than a generic one. This explanation may be not enough. Even among disease specific instruments differences are observed. It seems that 3 factors should be taken into consideration on this issue: the type of instrument, the domains of QoL investigated, and the sensitivity of the instrument to detect changes in quality of life and not just health status.

Spearman's correlation coefficient (r) between ADDQoL score and HbA_{1c} was -0.149. Thus, the use of ADDQoL-Gr in this research proved that there is a statistically significant negative correlation between levels of HbA_{1c} and mean weighted ADDQoL score ($p < 0.05$).

Higher HbA_{1c} levels were related with lower mean weighted ADDQoL score that is more negative impact of diabetes on quality of life (Table 28).

Table 28: ADDQoL scores and glycaemic control by level of HbA_{1c}

HbA _{1c} (%)	n	Mean	SD	p-value
6.5-7.0	382	-2.44	1.79	<0.0001
7.0-7.5	251	-2.45	1.68	
7.5-8.0	163	-2.62	1.76	
8.0-8.5	84	-3.16	1.77	
8.5-9.0	43	-3.23	2.28	
>9.0	56	-3.63	2.21	

13.1.8 QoL and disease duration

The relationship between QoL and duration of diabetes is unclear. There are studies that support the view that duration of diabetes and QoL are not significantly related (Jacobson et al. 1994; Hanestad, 1993; Parkerson et al., 1993; Peyrot and Rubin, 1997; Redekop, 2002). Contrary to this view, there are studies supporting that longer duration is related to lower QoL levels (Glasgow *et al.* 1997; Klein *et al.* 1998).

An early onset of diabetes may influence the course of personal development, may facilitate the long term adjustment to diabetes positively because the individual has time to increase management skills, alter personal perceptions, adapt to the demands of the disease, or in some cases has no memory of life without diabetes (Gafvels *et al.* 1993). In this respect it might influence QoL.

Moreover, the relationship between duration and QoL should not be considered as linear. This is because in the early stages of the disease (in the first few months), people feel more anxiety, depression and loss of control compared with people with

longer duration (Cassilieth et al. 1984). The finding suggests that psychological adaptation among patients with diabetes is effective.

The results of this work show a non-linear evolution of QoL. The phenomenon is apparent throughout the duration of the disease and not only during the first few months. Low levels of QoL are observed after the onset of the disease (-2.47), but this remains constant for the first 20 years (Table 29). From 21 to 40 years of duration the levels of QoL are even lower. The worst deterioration of QoL levels takes place between 21-40 years of duration (-3.45). What at first sight seems to be unexpected is that duration group >40 years of diabetes score slightly higher levels of QoL compared with the group of 31-40.

Table 29: ADDQoL scores and disease duration

Duration (years)	n	Mean	SD	p-value
0-10	406	-2.47	1.78	0.0005
11-20	311	-2.47	1.58	
21-30	175	-2.58	1.93	
31-40	59	-3.45	1.86	
>41	21	-3.30	2.38	

By looking more closely one might conclude that this phenomenon should be seen in parallel to other factors such as age, where people of 60 to 80 years of age appear to score higher than the 2 previous age groups.

13.1.9 Diabetes Dependent QoL and Marital Status

As far as QoL is concerned both types of diabetes patients are affected by marital status, with divorced people experiencing the lowest levels of QoL. The association between family and QoL is not attributed to differences on glycaemic control that one might expect among various marital categories, but is more related to psychological factors (Trief *et al.* 1998; Trief *et al.* 2001).

Respondents were classified into four categories as follows: Unmarried n= 195 (19%), married/partner n= 636 (61.9%), divorced/separated n= 57 (5.6%), Widow/er n=137 (13.3%). Data on family status for 2 respondents (0.2%) were missing.

Table 30: ADDQoL scores and marital status

Family Status	Mean	S.D	n	p value
Unmarried	-2.23	1.80	195	0.001*
Married/Partner	-2.68	1.82	636	
Divorced	-3.00	2.03	57	
Widow/er	-2.75	1.57	137	

Kruskal-Wallis test showed that there was a statistically significant difference on the mean weighted ADDQoL score regarding family status ($p=0.001$, see Table 30). Unmarried patients reported significantly higher ADDQoL score compared with the all other categories, revealing that the impact of diabetes on their quality of life was less negative compared with the others. Divorced people scored the lowest level of QoL (-3.00), followed by widow/ers (-2.75) and married or living with a partner (-2.68). The results concerning divorced and widowed people are in agreement with international literature, as these groups are in general more vulnerable to depression (Peyrot and Rubin, 1997; Jacobson *et al.* 1994; Connell *et al.* 1994; Murrell *et al.* 1983).

13.1.10 Diabetes Dependent QoL and Education

Respondents were classified into four categories as follows: Primary school (6-12 years) n= 391 (38.1%), secondary (12-15 years) n= 149 (14.5%), Lyceum (15-18 years) n= 266 (25.9%), university (>18) n=212 (20.6%). Data on education were not available for 2 respondents (0.2) respondents.

Education *per se* is an important determinant of health outcomes, independent of other determinants of health. Various writers have reported that less-educated patients score lower on all QoL dimensions compared with more highly educated ones (Glasgow *et al.* 1997; Rubin, 2000). The mechanisms for this correlation have not been adequately explained, but people with low education levels have low health

service utilisation rate and worse outcome in terms of complications (Van der Meer and Mackenbach, 1999).

Table 31: ADDQoL scores and Education

Education	Mean	SD	n	p value
Primary	-2.787	1.690	391	<0.0001*
Secondary	-2.869	2.056	149	
Lyceum	-2.666	1.914	266	
University	-2.125	1.648	212	

These findings are consistent to our expectations and the international literature. There is a statistically significant difference in the means of weighted ADDQoL scores between the education levels ($p < 0.05$). It can be observed that the mean weighted ADDQoL score for university graduates is significantly higher than the means of the other levels of education.

13.1.11 Diabetes Dependent QoL and Income

Income is considered by lay people in general as an important parameter in determining QoL (Brown *et al.* 2004: 17). The relationship between income, health status and QoL is a complicated issue. The mechanisms connecting the two are still under investigation. It has been suggested that low income is a decisive factor in type 2 diabetes prevalence (Connolly *et al.* 2008). There is also evidence that low income diabetes patients receive less care than high income patients (McCall *et al.* 2004). However, low income diabetes patients, even if they have good access to health care, have worse health outcomes compared with groups of higher income (Jotkowitz *et al.* 2006). They also report lower quality of life. (Glasgow *et al.*, 1997).

Various explanations have been given for this and the factors responsible vary from health behaviours (e.g. diet, smoking, physical activity), community factors (e.g. availability of healthy food, places to exercise), access to health care, and diabetes management (e.g. measurement of HbA_{1c}) (Brown *et al.*, 2004).

Respondents were classified into seven income clusters as follows: € 0-500 n= 199 (19.4), € 501-1000 n=305 (29.7%), € 1001-1500 n=275 (26.8%), € 1501-2000 n=100

(9.7%), € 2001-2500 n=43 (4.2%), € 2501-3000 n= 25 (2.4%), € > 3000 n=34 (3.3%). As expected, the number of missing data on this question was the highest among all questions reaching the number of 46 (4.5%). This is due to inefficiency of the tax authorities which in turn result to high numbers of tax avoiding citizens. There are reasons to believe that these missing data belong mainly to respondents with higher than average incomes, who according to publications are evading taxes more than any other income group (Matsaganis and Flevotomou, 2010; Vasardani, 2011; Artavanis *et al.* 2012).

Despite the fact that a high percentage of expenses is covered by social security, Spearman's correlation coefficient (r) between the mean weighted impact ADDQoL score and monthly salary showed a statistically significant positive correlation ($r = 0.188$, $p < 0.05$), meaning that higher salary was related with higher mean weighted ADDQoL score, that is less negative impact of diabetes on quality of life.

When the mean weighted impact is assessed for the various income groups it can be clearly seen the increase of QoL levels as income increases (Table 32).

Table 32: ADDQoL scores and Income

Monthly Income €	n	Mean	SD	p-value
0-500	199	-2.95	1.85	<0.0001
501-1000	305	-2.81	1.78	
1001-1500	275	-2.41	1.62	
1501-2000	100	-2.18	1.97	
2001-2500	43	-2.10	1.81	
2501-3000	25	-2.49	1.81	
>3000	34	-2.03	1.91	

13.1.12 QoL and Co-payments

The term co-payments in diabetes includes money spent for test-strips, needles, additional blood tests for HbA_{1c}, socks, shoes, glasses, and visiting consultants in the private sector. Co-payments in the treatment of diabetes is a major issue in the Greek health service. This could be attributed to inefficiencies of the national insurance

coverage for the particular disease, especially when sub-specialties of diabetology are needed.

It has been suggested that low income groups are sensitive to cost sharing as they spend a higher proportion of their income on out-of-pocket expenses than do higher-income patients (Newhouse, 1993; Gross *et al.* 1999). Also, patient co-payments are higher for people with type 2 diabetes, as social security does not cover most of the consumable goods and routine blood tests.

Spearman's correlation coefficient r between the ADDQoL average weighted score and the expenses for diabetes was low ($r = -0,076$) but statistically significant with a p value 0.015 ($p < 0.05$). The negative correlation shows that patients who spent more money for diabetes had poorer average weighted impact ADDQoL scores. This is expected taking into consideration the flat coverage of expenses from the social security system (i.e. a fixed allowance irrespectively of diabetes severity), which does not favour patients with low levels of health and QoL.

13.1.13 QoL by Diabetes Centre

There was evidence of a statistically significant difference in the means of weighted ADDQoL scores between hospitals. Thus, post hoc tests (Mann-Whitney U test with Bonferroni correction) showed that the mean weighted ADDQoL score for IKA Salonica 1 was significantly higher than the means of Evangelismos, Alexandra and Kavala hospitals. Also the mean weighted ADDQoL score for Hippocraton Salonica was significantly higher than the mean of Laiko hospital. There was no significant difference among the other hospitals (Table 33).

There is no obvious explanation for these intriguing differences, and they need to be investigated further. The answer to the question might lie with the characteristics of the respondents rather than those of the hospital, and probably includes medical as well as social factors.

Table 33: ADDQoL scores by diabetes centre

Hospital Centre	Mean	SD	n	p value
IKA Salonica 1	-2.176	1.208	213	<0.0001*
IKA Salonica 2	-2.799	1.527	47	
Hippokration Sal.	-2.447	1.675	264	
Polycliniki Athens	-2.481	2.183	89	
Laiko Athens	-3.320	2.466	60	
Evangelismos Ath.	-2.809	2.043	194	
Alexandra's Athens	-3.008	1.833	96	
Kavala Gen. Hospit.	-3.069	1.781	64	

The sample was analysed by testing site and each site was analysed by the medical and demographic characteristics of its sample. All the results of the analysis can be seen in tables 8 and 9 of this thesis. At this point a simple juxtaposition of three hospital results show that demographic and diabetes-related variables could be seen as determinants of QoL not only for the individual, but for groups of people at a macro level.

Polycliniki of Athens which has the best mean weighted impact among all hospitals and the second best among all sites has the majority of its respondents having Type 1 diabetes (69.7%). It also has the lowest mean age among all sites (43.89). Moreover it has the highest percentage of unmarried people (40.4%) and the highest percentage of university graduates (50.6%). Patients with diabetes-complications were lower than average with 21.3% among the sample (average 29.7%). Polycliniki patients were less hospitalised than any other site's (14.6%). It also attracts the highest income people among all sites.

Kavala's sample is on the other extreme of the spectrum. It has the poorest patients, the highest percentage of hospitalisation (31.3%), the second worst percentage of complications (48.4), the lowest educational level with only 1.6% university graduates, and low percentage of unmarried people (6.3%). The mean age of 66.9 years was also unfavourable for Kavala's hospital.

Laiko of Athens, which has the lowest scores, is a university hospital and its diabetes centre is highly respected among people with diabetes. The low score should be attributed to the high number of complications. Laiko is the only diabetes clinic among the eight research sites that has a special diabetes-foot section that it accepts patient with developed foot problems and sometimes amputated. 60% of its patients appear to have at least one diabetes-complication while other neighbouring hospitals (e.g. Polycliniki or Alexandra's, which is less than one mile away) complications are around the 21% region.

13.1.14 QoL and place of residence

Next, the hospitals were summarized in 3 categories depending on the geographical area they belong. Applying the Kruskal-Wallis test it resulted that there was a statistically significant difference in the means of weighted ADDQoL scores between the 3 areas. Post hoc tests concluded that the mean weighted ADDQoL score for Thessaloniki hospitals was significantly higher than the means of the hospitals in Athens and Kavala (Table 34). There was no significant difference between Athens hospitals and Kavala's hospital.

There was evidence that there is a statistically significant difference in the means of weighted ADDQoL scores among test sites. Thus, post hoc tests (Mann-Whitney U test with Bonferroni correction) comparison concluded that the mean weighted ADDQoL score for IKA-Salonica1 was significantly higher than the means of Evangelismos, Alexandra's and Kavala hospitals. Also the mean weighted ADDQoL score for Hippocraton-Salonica was significantly higher than the mean of Laiko hospital. There was no significant difference among the other hospitals. There was no obvious answer to these differences. Some conflicting findings among research sites might be due to a number of competing influences that should be investigated further.

Table 34: ADDQoL scores by geographical area

Hospital Centre	Mean	SD	n	p value
Salonica	-2.369	1.497	524	<0.0001*
Athens	-2.856	2.100	439	
Kavala	-3.069	1.781	64	

People living in rural areas appear in general as having higher social integration, and are more satisfied with their environments, regardless of material disadvantages (Brown *et al.* 2004). These two are major components of QoL, thus they usually report higher levels of QoL and well-being. This is not the case of people with diabetes.

Respondents from the Kavala site reported the lowest QoL (-3.07). Kavala, is a semi-urban/rural area of around 60,000 inhabitants. The diabetes clinic of Kavala hospital attracts people from the rural area around Kavala, is not a diabetes center but part of the internal medicine clinic, and accepts patients only one day per week. The QoL score difference observed between the sites of Kavala and Thessaloniki (-3.07 and -2.37) is substantial for two cities with a distance of two hours driving. This finding was expected and confirms the research hypothesis, as diabetes is a disease that needs high levels of medical attention, health education of the diseased, and easy access to diabetes centres, factors that are not easily met in rural Greece.

What was not expected initially was the difference between Salonica and Athens (-2.37 and -2.86 respectively), because the two cities have similar establishments as far health services are concerned. An initial explanation could be that almost half of the total Salonica sample (260 out 524) was recruited from social security primary clinics (IKA), which usually do not attract serious cases of diabetes. However, the 2nd IKA has lower scores than Hippocraton and substantially lower than IKA 1. Taking into consideration that the mode of the test administration was exactly the same between the two IKA sites the explanation of the differences could lie with the gravity of the cases that each site attracts, which in turn could be attributed to subjective factors, such as the reputation of the medical personnel, among diabetes patients.

Another explanation for the overall difference between Athens and Salonica that should be taken into consideration, although not of a scientific nature, could be one of a cultural nature. It is widely accepted in Greece that Salonica is a place for entertainment, night-life, and low levels of anxiety. The proverbial “relaxed” life-style of its residents constitutes a joke even in comedies. This common view is supported by the findings of this research.

13.1.15 QoL and visits to consultants

The relationship of QoL and visits to consultants does not seem to have any great importance in explaining QoL, as it is related to the issue of complications and no significant conclusions can be drawn out of it. However, regarding the specialties that the patients visited the previous year due to their diabetes, there was evidence that there is a statistically significant relationship between them and the quality of life measured by ADDQoL-Gr ($p < 0.05$) [Table 35]. Specific, post hoc tests (Mann-Whitney U tests with Benferroni correction) showed that the mean weighted ADDQoL-Gr score for patients visited the cardiologist was statistically significant lower than the mean of the patients visiting the eye doctor ($p < 0.0001$). This might be an indication that patients visiting cardiologists due to diabetes, *ceteris paribus* score lower for their quality of life compared with the patients who visit the eye doctor.

Table 35: ADDQoL scores and visits to consultants

Specialty	n	Mean	SD	P-value
Cardiologist	536	-2.80	1.78	0.004*
Ophthalmologist	348	-2.45	1.90	
Nephrologist	14	-2.69	2.23	
Podiatrist	3	-3.76	1.98	
Psychiatrist	6	-2.35	2.04	

* Indicates statistically significant difference

13.1.16 QoL and Hospitalisation

The presence of co morbidity is a decisive factor for QoL. A comorbidity is a disease or condition that coexists with a primary disease but also stands on its own as a specific disease. Common co-morbidities of diabetes are hyperlipidemia, cardiovascular disease, peripheral vascular disease, renal failure and others.

Mann-Whitney U test revealed that patients who, during the last year were hospitalized (even for one night) for any reason, had significantly lower ADDQoL average weighted impact scores ($p < 0.05$), compared with those who didn't spend any night in the hospital (Table 36).

Table 36: ADDQoL scores by hospitalisation

Hospital visit during last year	Mean	SD	n	p value
Yes	-2.96	1.96	224	0.006*
No	-2.52	1.76	797	

* indicates statistically significant difference

Co morbidity and the resulting hospitalisation is the cause of high medical expenses and low QoL. Special attention should be paid to diabetes management programs in order to incorporate treatment for co morbid conditions that would reduce hospitalisation risk.

13.1.17 QoL and Membership in a diabetes group

The last question of the personal data questionnaire concerned the probable membership of the respondent in any diabetes group. There are many local groups in Greece that act as pressure groups as well as diabetes education centres. However, the number of patients joining those groups is unexpectedly low.

The groups function as Non-Governmental-Organisations, and strangely enough are divided into two secondary level Federations. One Federation is part of the National Confederation of People with Disabilities (tertiary federation and member of the European Forum for People with Disabilities). It functions as the major pressure group for diabetes patients' interests. At the same time it organises diabetes-

management programs mostly with the voluntary participation of Greek diabetologists. The other is of less importance, more of a governmental nature, smaller in size, represents mostly groups created by the Greek Centre for Diabetes, which as a government organisation is recognised by the International Diabetes Federation.

Table 37: ADDQoL scores and membership in diabetes groups

Member of a diabetes group	n	Mean	SD	p-value
Yes	92	-2.34	2.08	0.011*
No	930	-2.65	1.79	

* indicates statistically significant difference

Mann-Whitney U test revealed significantly lower average weighted ADDQoL scores ($p < 0.05$) in patients who were not member of a diabetes group compared with those who were (Table 37). The fact that people who are members of a diabetes group have higher levels of QoL could be attributed to better diabetes management, which in turn could be attributed to the diabetes education lessons, provided by the diabetes groups on a voluntary basis, by some distinguished diabetologists, as well as by diabetes patients with high level of diabetes education.

On the other hand someone could argue that people join the groups because they are already interested in their diabetes and its management. The type of this survey does not allow the location of the causal link between the two. However, although the direction of causality cannot be easily determined, the relationship between the two cannot be disputed.

13.2 Discussion

As a general remark it should be mentioned that there is not a single factor that could be considered as the only determinant of diabetes-dependent QoL. In all cases other confounding factors have to be taken into consideration in order to assess the influence of a factor in determining QoL.

Age, plays a very important role in QoL determination with an inversely proportional relationship existing between the two. However, this statement should not be considered as a general principle, because when other confounding factors, such as gender or diabetes duration, are taken into consideration the association of age with QoL takes a different form and it is not unidirectional any more.

Gender *per se* does not play an important role in determining the QoL of a diabetes patient. This applies to both types of diabetes. The results of this research seem to provide an answer to the question of the influence that diabetes type has on QoL (12.1.1). It was proved that this relationship is not linear and changes with age to different directions not only for the two types of diabetes, but between different age clusters of the same diabetes type.

Glycaemic control is another case of a determinant that should not be examined in isolation from other factors. In general, high levels of HbA_{1c} have a negative effect on QoL. However, this factor should not be considered as predictor of QoL. Other confounding factors, such as complications caused from high HbA_{1c}, or even treatment regimen, which in itself plays an important role, should be examined before the specific weight of glycaemic control in determining QoL is decided.

Complications caused by diabetes should be considered as the most influential factor in determining the level of QoL. This, as a general statement, is in agreement with international literature. The novelty of this research is the finding that microvascular complications have the most negative impact on QoL, contrary to the mainstream belief that macrovascular complications mainly coronary heart disease are responsible for low levels of QoL.

Another unique finding is the importance of erectile dysfunction on determining QoL. Respondents with ED report lower QoL not only compared with patients with other complications, but they score even lower than people with two or more complications.

Diabetes as a chronic condition demands good knowledge of the disease as well as good management. General education seems to help the patient in the disease understanding process because the results showed that education is directly proportional to QoL; as education level increases QoL level moves to the same direction.

Good management is also related to marital status with married with divorced people reporting the lowest levels of QoL. Married people should be expected to enjoy higher levels of QoL compared with other people. However, the results show that unmarried people enjoy higher QoL than married or people living with a partner. Two factors should be taken into consideration: the first one is that unmarried people are usually younger than all other categories and second that Greek society is still family centred lacking help from any other social networks, while family is child-centred. The meaning of child is used in an extended sense, as children in Greece seldom leave the family of origin prior to marriage or studies (Tsamparli, Kounenou 2004). This, in relation to the well established fact that children living with families receive care from parents mainly from mothers (Faulkner, 1996; Kiess *et al.*, 2001), explains the astonishing at first sight fact that unmarried people suffering from a chronic disease that needs good management enjoy higher levels of QoL compared with other sub-categories.

Some interesting issues emerged when QoL was examined by diabetes centre. There were significant differences among the testing sites concerning the general level of QoL. A first conclusion might be that the differences observed are because of existing differences in the composition of the samples. If this is the case, another question arises and that is why each clinic attracts, to a great extent, populations with certain demographic and/or medical characteristics, which in turn determine the overall outcomes. The explanation of this phenomenon should not be considered as a result of a central diabetes-care planning as there is no such provision in the health system. It should be attributed to personal scientific interests and initiatives of the medical staff, which “specialise” in a particular type or aspect of diabetes.

On the other hand, diabetes patients are informed about the “sub-specialties” of diabetes centres and demand care accordingly. Thus, one could claim that there is an interactive relationship between diabetes centres and certain clusters of diabetes population that balances the demand and supply of diabetes care. This balance resembles more the characteristics of a free market, than a rationally planned health system. This finding should initiate a further investigation based on and looking for a qualitative distribution of diabetes services in order to rationalise diabetes care and achieve a balance between the distribution of services and the demand for them.

The incoherent distribution of services is also proved by analysing the sample by complication and its impact on QoL. Erectile dysfunction (ED) has the highest negative effect on QoL. The prevalence of the complication among male diabetes patients globally varies from 26% to 63.6% (see 13.1.4). In of this survey ED was reported only by 6.9% of the total male sample. Even by taking into consideration any probable cultural barriers to report ED because of the sensitivity of the matter for a male respondent, the percentage is still unacceptably low compared with results from the international literature. The answer again should be investigated in the structure of diabetes-care provision. None of the hospitals used as testing sites is specialised in treating ED for a male diabetes patient. The result is that some patients who can afford the expenses are turning for treatment to the private sector, while others visit urologists of the NHS. However, urology is a surgical specialty and receiving treatment from someone not specialised in diabetes might have uncertain results. This finding should be used, in relation to the distributional issue discussed in the previous paragraph, to the direction of restructuring diabetes care in Greece and create specialised centres of clinical excellence for diabetes patients.

Income level as a determinant of diabetes-depended QoL is well documented in international literature. The results of this survey were no exception to the rule. However, an interesting point arises when co-payments for diabetes are taken into consideration. There is a reciprocal relation between money spent from family income and level of QoL. The problem becomes severe for low income patients, who cannot afford the co-payments, as they represent a substantial proportion of their incomes. It has been reported that co-payments reduce service utilisation among low

income patients with high medical risks having adverse effects on their health status (Manning *et al.*, 1987; Robinson, 2002; Gruber, 2006; Lostao *et al.* 2007). This is well established and many countries have introduced exemption schemes for low income patients (Rosen *et al.*, 2011; Carelli 2012). There is evidence that diabetes patients, especially those without complications, following the general rule, reduce care when co-payments increase (Babazono *et al.*, 2005). In Greece during the last four years co-payments for consumables (test strips, lancet devices for finger-pricking etc.) and medication aiming to avoid complications (e.g. for hypertension or cholesterol) have risen for type 2 diabetes patients from 10% to 25%, which could be considered unbearable for low income patients. The levels of co-payments, as well as the flat rates of reimbursement, when patients have to pay the provider first and then apply to the health authorities for reimbursement, have to be reconsidered.

PART VI: Diabetes and Health Status

Chapter 14: Diabetes and the SF-36

14.1 Introduction

An assessment of the impact of diabetes on health status is examined in this chapter, using the latest version of a generic measure, the SF-36. Three points should be made before the assessment begins: First, it should be noted that the conceptualisation of HRQoL of the SF-36 is a “disease burden” one that includes distress due to symptoms, treatment, or complications, contrary to the ADDQoL which approaches the concept from a different angle that of the patient’s perception of QoL i.e. how diabetes interferes with the life of the individual and how he/she imagines life without diabetes. Second, there are doubts about the sensitivity of the SF-36 in detecting changes in QoL of people with diabetes (Hill-Briggs *et al.* 2005). Third, it should be noted that the SF-36 is a standardised measure and therefore does not take into consideration the applicability or the relative weight that each domain has for the individual patient. The underlying assumption for the lack of weighting is that patients find it impossible to put comparative values on important life domains ((Carr and Higginson, 2001).

The SF-36 was not used as an alternative QoL measure, as many researchers do in international literature using the terms “Quality of Life” and “health status” interchangeably, but as an auxiliary one. Health status in this project was considered only in the capacity of being a major component of the broader term “Quality of Life” and as such should be examined. In this sense result analyses were not as detailed as with the ADDQoL-Gr, but more of a restricted nature.

However, there are four reasons for using the SF-36:

- First and foremost, the assessment of health status was an aim of this project after that of QoL. The use of a generic measure, it gives the opportunity to compare health status of people with diabetes in Greece with other groups and controls.

- Second, a widely accepted criterion should be used in order to assess the validity of the ADDQoL-Gr. The criterion of the two global questions, used by the developers of the original ADDQoL, although used in this research, was not considered sufficient for the establishment of the Criterion Validity.
- Third, the prevailed view among researchers is that a generic as well as a disease-specific instrument should be used in order to obtain reliable results.
- Fourth, the SF36 is considered by many writers as a “compatible” to ADDQoL instrument.

14.2 The domains of SF-36v2

The SF-36v2 represents an improvement of the original, benefited from the hindsight of the SF-36 numerous applications. It differs from the original in question wording and layout, respond choices, scoring, and comparability with translations and cultural adaptations.

The SF-36v2 contains 36 questions in eight health domains (Ware *et al.*, 2007). These domains are:

- Physical Functioning (PF): It contains 10 items (3a to 3j), which refer to the performance of physical activity such as self-care, walking, climbing stairs, etc.
- Role Physical (RP): It is a 4 item dimension (4a to 4d), referring to the degree to which a person performs or has the capacity to perform activities corresponding to age, gender, job, housework etc. It examines possible limitations imposed on the kind of work or other activities, the time that might be spent on them, as well as the difficulty to perform them.
- Bodily Pain (BP): It is a 2 item scale (7 and 8). One item refers to the intensity, frequency, duration and the second one to the limitations that pain imposes on the activities of an individual.
- General Health (GH): It consists of 5 items (1 and 11a to 11d) and it refers to the perception of an individual's overall prior and current health, and resistance to illness.

- Vitality (VT): 4 items (9a, 9e, 9g, and 9i) constitute this scale which investigates energy, fatigue and tiredness.
- Social Functioning (SF): It consists of 2 items (6 and 10). Social functioning is the degree to which an individual can develop, maintain and nurture social relationships (family, friends, marital and sexual functioning, and neighbours).
- Role Emotional (RE): 3 items (5a to 5c) refer to the functional impact that emotional problems have on the individual, further to the ones imposed by physical health, measured by the RP scale.
- Mental Health (MH): The scale consists of 5 items (9b, 9c, 9d, 9f, and 9h). Each item refers at least to one of the four mental health dimensions i.e. anxiety, depression, loss of behavioural-emotional control, and psychological well-being.

The summary of the eight domain scores are referred as Physical Component Summary (PCS) and the Mental Component Summary (MCS). They are derived and calculated with Factor Analysis, the Principal Component Analysis.

14.3 Method

The administration method of the questionnaire has been described in chapter 9. The collected data were introduced for statistical analysis and results for aggregate scores of the eight domain, as well as summary scores for the two components (PCS and MCS) were calculated. The QualityMetric Health Outcomes Scoring Software 2.0 (Saris-Baglama et al., 2007) was used, complimentary provided by QualityMetric Incorporated.

14.3.1 Scoring

All domain scales contribute to the scores of both the Summaries. However, the PF, RP, BP, and GH scales have greater physical factor content, compared with the other

four domains and constitute the PCS measure of the instrument. The remaining four, i.e. VT, SF, RE, and MH might be considered as having greater mental factor content and constitute the MCS measure. Some scales correlate more than others with both components: VT correlates almost equally with them, followed by GH, and SF which correlate with both, although the first correlates more with the physical component and the second with the mental one (*ibid*).

The original SF-36 used for all eight health domains scores ranging from 0 to 100. However, the two summary components i.e. the Physical Component Summary (PCS) and the (MCS) have always used norm based scores. The difficulties emerging in comparing the health domains with the summary components forced the developers to establish in the SF-36v2 a norm based scoring (NBS) system (Ware *et al.*, 2007).

Norm-based scoring (NBS) transformed the initial 0-100 scores to a standardised metric system with a mean of 50 and a standard deviation of 10, allowing comparisons between health domains and summary component scores. The mean was initially based on the 1998 US general population (*ibid*). However, the software received from QualityMetric has revised the general population means with the 2009 data, thus comparisons have been made with the latest available data. The term “general population” embraces the population at large not only the healthy ones but it includes diseased and invalid persons. Consequently, the samples of the general population are always healthier than any group of patient samples.

The fact that the means are based on American general population raised questions about the value of the scores. In a personal communication with QualityMetric officials it was clarified that the use of the general population means was a choice made to facilitate international comparisons.

14.4 Results

14.4.1 Health Status for total sample

In all eight domain scales of the SF-36v2 Norm Based Scores (NBS), as well as in the two summary components (PCS and MCS) scores were lower than norm (50) that is lower compared with those without diabetes, indicating a poor health status for people with diabetes in Greece. This is consistent with all previous research on this field in various countries (Jacobson *et al.*, 1994; Alonso *et al.*, 2004; Wee *et al.*, 2005; Chittleborough, 2006).

However, what is worth mentioning here is that mental health score (MCS) is lower than the PCS score. This contradicts previous research findings where diabetes patients report significantly lower scores on physical rather mental health. In the IQOLA project (Alonso *et al.* 2004), across eight countries diabetes-patients in all countries reported greater impact on physical health rather than mental. Similarly, in the SF-36 user's manual disease specific norms, mental health among diabetes patients scores higher than physical health (Ware *et al.* 2007). The causes for this dissimilarity probably cannot be found in the disease *per se* but to the unprecedented crisis, and the resulting anxiety or even depression that had already emerged during the fieldwork period, and affected Greek society as a whole.

14.4.2 Gender and HS

It was observed that male diabetes patients report a higher health status in both components as well as in all eight domains (Table 38). This consists with the prevalent view among researchers that men with diabetes enjoy a higher health status compared with women (Glasgow *et al.*, 1997; Kind *et al.*, 1998; Woodcock *et al.*, 2001; Taft *et al.*, 2004; Chittleborough *et al.*, 2006, Quah *et al.*, 2011; Schunk *et al.*, 2012).

Table 38: SF-36 scores by gender across total sample

	Component Summaries		SF-36 Domains							
Gender	PCS	MCS	PF	RP	BP	GH	VT	SF	RE	MH
Male	47.7	45.3	46.2	46.0	50.5	44.7	51.5	46.6	45.1	43.0
Female	44.5	42.7	42.0	43.0	44.5	42.1	46.4	44.3	41.6	40.4
Total	45.8	43.8	43.7	44.2	46.8	43.1	48.4	45.2	43.0	41.5

PCS: Physical Component Summary; MCS: Mental Component Summary; PF: Physical Functioning; RP: Role Physical; BP: Bodily Pain; GH: General Health; VT: Vitality; SF: Social Functioning; RE: Role Emotional; MH: Mental Health.

14.4.3 Age and HS

As expected, age was another factor influencing the level of Health Status, with an inverse relationship between age groups and HS level (table 40). As age increases, the level of HS falls, with PF exhibiting the worst pattern of deterioration among all domains. This could be considered as a common sense finding. However, two important points emerge from this table:

The first one is that the age groups between 18 and 50 reported physical health in a positive or normal manner. This indicates that a chronic disease like diabetes does not contradict good health perceptions. Although, at first sight, this seems unrealistic there are previous research findings corroborating this fact either for diabetes (Hanestad 1993) or other chronic disease patients (Pearlman and Uhlmann, 1988). Edelman *et al.* (2002) argued that QoL for newly diagnosed people with diabetes and throughout the following year was similar to people without diabetes.

The second and possibly most intriguing point that could be observed here is the changes occurring between physical and mental health as age increases. Younger persons reported no impact of diabetes on their physical health (PCS, PF, RP, BP, VT), but a serious impairment on mental health (MCS, RE, MH), something not observed among older patients. The same observation was reported by Glasgow in 1997, but no explanation has been given. Probably, the explanation lies with the “response shift” phenomenon, analysed in chapter 3, which refers to the change in the meaning and importance of one’s evaluation of certain domains in life, as a result of a recalibration of internal standards and reconceptualization of the domains’ meaning.

Repeating the age analysis controlling for gender the results were again unfavourable for female patients, while the phenomenon of “response shift” is still observable (Table 39).

Table 39: SF-36 scores by age and gender across total sample

Age (years)	Component Summaries		SF-36 Domains							
	PCS	MCS	PF	RP	BP	GH	VT	SF	RE	MH
Male										
<31	54.13	45.25	54.26	50.55	54.68	50.12	58.10	50.02	45.92	42.60
31-40	52.72	43.26	52.71	49.68	54.33	46.21	53.50	47.03	44.15	42.43
41-50	50.75	44.26	50.74	49.51	51.90	44.52	52.27	47.56	46.31	41.59
51-60	48.24	45.92	46.52	46.94	50.60	45.66	51.90	48.15	45.18	43.34
61-70	46.19	46.34	44.84	45.17	48.96	43.77	50.95	46.66	45.59	43.62
71-80	44.10	45.49	40.57	42.70	48.65	42.99	48.68	43.96	44.60	42.81
>80	42.19	45.95	37.03	39.88	48.71	44.68	46.04	42.36	45.38	42.99
Female										
<31	51.44	44.81	51.61	49.98	52.78	45.59	53.29	48.22	47.50	41.54
31-40	50.65	42.84	50.62	48.88	50.67	45.31	49.43	46.14	45.30	41.07
41-50	48.24	44.84	46.81	48.74	46.81	46.09	50.61	47.19	44.93	42.29
51-60	45.07	43.50	42.37	42.78	44.83	43.69	49.34	45.90	41.60	40.47
61-70	43.86	42.28	41.36	42.81	43.61	41.04	45.35	43.54	40.91	40.65
71-80	40.30	41.68	36.13	38.47	40.70	39.60	42.20	42.11	39.30	39.42
>80	38.60	41.89	33.82	35.47	40.76	38.92	41.87	40.97	37.03	40.96
Total										
<31	52.76	45.03	52.91	50.26	53.72	47.81	55.66	49.10	46.72	42.06
31-40	51.56	42.90	51.53	49.21	52.22	45.62	51.12	46.43	44.67	41.61
41-50	49.15	44.63	48.23	49.02	48.65	45.52	51.21	47.32	45.43	42.04
51-60	46.25	44.38	43.90	44.37	47.00	44.40	50.26	46.68	42.97	41.53
61-70	44.79	43.89	42.74	43.75	45.74	42.12	47.57	44.78	42.76	41.83
71-80	41.71	43.09	37.77	44.04	43.64	40.85	44.60	42.80	41.27	40.68
>80	39.85	43.30	34.94	37.00	43.52	40.93	43.32	41.45	39.93	41.67

PCS: Physical Component Summary; MCS: Mental Component Summary; PF: Physical Functioning; RP: Role Physical; BP: Bodily Pain; GH: General Health; VT: Vitality; SF: Social Functioning; RE: Role Emotional; MH: Mental Health.

14.4.4 Type of Diabetes and HS

There are significant differences concerning the physical domains between type 1 and 2 diabetes. Type 2 patients report substantially lower scores both in physical domains and physical component summary (Table 40).

A noteworthy point here is that although patients with type 1 diabetes report a close to normal PCS and PF, their MCS and MH domains are well within the “poor health” region of the SF-36, equally low with Type 2 diabetes.

14.4.5 Treatment of diabetes and HS

There are not significant differences among different treatment regiments according to the SF-36 results (Table 40). Respondents taking insulin scored slightly higher on physical domains and slightly lower in mental health. People on “diet only” score low especially in the mental health areas of the SF-36. This proves that the burden of diabetes is higher to people not receiving any pharmaceutical treatment, probably due to higher diet restrictions.

Table 40: SF-36 scores by Diabetes type and treatment

Diabetes Type	Component Summaries		SF-36 Domains							
	PCS	MCS	PF	RP	BP	GH	VT	SF	RE	MH
Type 1	49.93	43.50	50.37	48.27	50.51	46.34	51.89	47.30	44.67	41.73
Type 2	43.58	43.09	41.31	42.45	45.33	42.04	46.96	44.28	41.98	41.08
Treatment										
Insulin	46.23	43.23	44.00	44.40	47.43	42.93	48.38	45.07	42.72	41.03
Tablets	45.30	44.56	43.22	44.11	46.27	43.49	48.61	45.64	43.47	42.09
Diet only	45.57	41.53	42.25	41.76	46.12	44.26	48.32	42.05	40.87	39.48

PCS: Physical Component Summary; MCS: Mental Component Summary; PF: Physical Functioning; RP: Role Physical; BP: Bodily Pain; GH: General Health; VT: Vitality; SF: Social Functioning; RE: Role Emotional; MH: Mental Health.

14.4.6 Glycaemic Control and HS

Poor glycaemic control had a negative effect on health status. With the exception of BP and VT the effect was moderate to high on the other six domains of the SF-36. Patients belonging to the 8.5 – 9.0 group were affected most on all eight domains, including BP and VT (Table 41).

Table 41: SF-36 scores across total sample by level of Glycaemic Control

HbA _{1c}	Component Summaries		SF-36 Domains							
	PCS	MCS	PF	RP	BP	GH	VT	SF	RE	MH
6.5-7.0	46.78	44.80	44.48	45.12	47.33	44.87	49.64	45.93	43.46	42.42
7.0-7.5	45.15	43.66	43.23	43.11	46.63	42.73	47.69	45.84	42.72	41.14
7.5-8.0	46.15	41.63	44.54	44.13	45.78	42.03	47.42	44.33	41.89	40.26
8.0-8.5	46.16	43.48	42.56	44.96	48.80	43.22	48.40	43.83	44.09	40.87
8.5-9.0	37.48	40.88	36.60	36.99	41.41	37.81	41.12	39.83	40.47	39.75

PCS: Physical Component Summary; MCS: Mental Component Summary; PF: Physical Functioning; RP: Role Physical; BP: Bodily Pain; GH: General Health; VT: Vitality; SF: Social Functioning; RE: Role Emotional; MH: Mental Health.

14.4.7 Disease duration and HS

Table 42 shows that longer duration of diabetes was not associated with any significant changes in physical and mental health, as measured with SF-36. This result is in agreement with previous research (Jacobson *et al.*, 1994; Hanestad, 1993; Parkerson *et al.*, 1993; Peyrot and Rubin, 1997; Redekop, 2002).

Table 42: SF-36 scores by duration of diabetes across total sample

Years	PCS	MCS	PF	RP	BP	GH	VT	SF	RE	MH
0-10	47.15	44.95	44.19	45.72	48.22	45.22	54.26	45.73	44.40	41.02
11-20	47.60	44.63	43.94	46.37	50.95	46.01	48.83	46.03	45.28	41.91
21-30	46.27	44.50	43.20	45.05	48.53	44.47	48.01	46.59	44.36	41.53
31-40	49.03	43.73	47.05	47.74	50.34	44.20	52.48	45.93	43.97	41.28
>40	46.53	46.08	45.49	46.14	47.92	43.92	50.27	47.54	46.61	42.37

PCS: Physical Component Summary; MCS: Mental Component Summary; PF: Physical Functioning; RP: Role Physical; BP: Bodily Pain; GH: General Health; VT: Vitality; SF: Social Functioning; RE: Role Emotional; MH: Mental Health.

14.4.8 Diabetes Complications and HS

In accordance with literature that examined QoL of diabetes patients using the SF-36, people with complications report serious impairments in almost all SF-36 domains. The deviation between previous findings in literature, concerning coronary heart disease, that was observed in the ADDQoL-Gr results (chapter 13.1.4), is still

observable here (Table 43). The existence of myocardial infarction, contrary to the findings of other researchers using generic measures (Lloyd *et al.*; Wandell *et al.*, 1998; Hart *et al.*, 2003; Wandell, 2005), instead of having the most serious effect on health status, does not seem to impair most health domains seriously.

This fact was investigated further across literature and the only similar result was found at a publication concerning the diabetes population of a small town of the Greek island of Lesvos. The project, took place in Plomari, a town of less than 6000 inhabitants and a sample of 229 diabetes patients (Papadopoulos *et al.*, 2007). This is the only attempt to assess QoL, in the form of health status, of a Greek diabetes population using the SF-36. However, no conclusions could be drawn from this project because there are some considerations about the reliability of results. This is not only because of the restricted catchment area, but because there are not any diabetes services provided in Plomari health centre, the sample was recruited using medical records concerning prescriptions of diabetes-medication, there is no physician among its medical staff specialised in diabetes, and finally the SF-36 although it is a self-reported instrument was administered by trainee physicians during interviews with the patients.

Table 43: SF-36 scores by diabetes caused complications across total sample

Complication	PCS	MCS	PF	RP	BP	GH	VT	SF	RE	MH
All Complications	41.55	41.75	39.75	41.07	43.22	38.78	45.15	42.18	40.28	39.50
Visual Impairment	41.18	41.24	39.18	40.52	42.54	38.43	44.34	42.65	39.18	38.98
Myocardial Infarct.	46.49	46.00	43.66	45.93	50.38	41.66	53.34	44.81	42.89	45.15
Nephropathy	41.10	40.51	39.55	41.59	42.70	34.20	45.47	42.30	37.13	39.36
Amputation	42.83	49.20	39.68	40.69	52.73	44.94	47.65	43.97	50.36	45.64
Erectile dysfunction	50.20	41.82	46.54	49.30	52.32	42.26	49.63	42.30	43.98	41.39
Other	39.27	41.45	38.81	39.14	40.43	39.13	43.30	39.95	41.85	38.13

PCS: Physical Component Summary; MCS: Mental Component Summary; PF: Physical Functioning; RP: Role Physical; BP: Bodily Pain; GH: General Health; VT: Vitality; SF: Social Functioning; RE: Role Emotional; MH: Mental Health.

14.4.9 Income and HS

There were significant and relatively large differences between respondents having different income levels. Low income people report low levels of HS both in physical as well as mental health. As income increases HS increases in both summary scores as well as in all health domains, reaching near-normal or normal levels for physical health for people with an income higher than €1500. Mental health however, remains at low levels for all income level groups.

Table 44: SF-36 scores by family income across total sample

Income (€)	PCS	MCS	PF	RP	BP	GH	VT	SF	RE	MH
0-500	44.93	41.33	40.76	43.62	44.73	41.91	16.83	43.79	40.21	38.87
501-1000	44.88	42.49	42.16	42.71	45.71	42.02	17.11	44.07	41.86	39.97
1001-1500	45.31	45.51	44.12	43.92	47.65	42.93	18.86	45.77	44.51	43.36
1501-2000	47.28	46.99	46.58	46.43	48.09	46.97	20.90	48.20	46.44	44.24
2001-2500	51.15	47.14	50.62	50.11	54.14	48.80	22.45	49.48	47.33	45.75
2501-3000	49.84	46.05	49.85	48.75	52.01	45.34	22.95	47.98	45.89	44.45
>3000	50.35	45.24	49.97	48.71	50.45	46.62	25.54	47.27	45.52	42.46

PCS: Physical Component Summary; MCS: Mental Component Summary; PF: Physical Functioning; RP: Role Physical; BP: Bodily Pain; GH: General Health; VT: Vitality; SF: Social Functioning; RE: Role Emotional; MH: Mental Health.

14.4.10 Family and HS

As in the QoL results single and divorced people represent the two ends of the spectrum. Single people enjoy the highest health status, while divorced score low at least in mental health domains (Table 45).

14.4.11 Education and HS

It is a well known fact for general population since the findings of the Black Report in 1980 that health status increases along with educational level (Townsend and Davidson, 1982).

Table 45: SF-36 scores by marital and educational status across total sample

Marital Status	PCS	MC S	PF	RP	BP	GH	VT	SF	RE	MH
Single	50.33	44.48	50.37	48.72	51.61	46.22	53.58	47.94	45.62	42.75
Married	45.60	43.86	43.11	44.12	46.95	43.23	48.16	45.27	42.95	41.57
Divorced	45.99	40.45	44.32	42.60	46.79	39.62	48.10	41.98	41.62	37.79
Widowed	41.05	43.10	38.25	39.62	40.86	40.55	44.03	43.18	40.73	40.81
Level of Education										
Primary	42.48	42.52	39.02	41.53	43.42	40.45	44.65	43.70	41.26	39.98
Secondary	46.09	42.07	43.80	42.33	47.43	42.79	48.68	43.77	40.87	40.37
Lyceum	47.35	45.17	46.96	45.89	47.76	44.53	51.03	46.62	44.58	42.94
University	50.19	45.43	49.04	48.64	52.06	47.11	52.54	47.79	46.06	43.11

PCS: Physical Component Summary; MCS: Mental Component Summary; PF: Physical Functioning; RP: Role Physical; BP: Bodily Pain; GH: General Health; VT: Vitality; SF: Social Functioning; RE: Role Emotional; MH: Mental Health.

Table 45 shows that diabetes patients are no exception to this rule. Health Status increases in all summary and domain scores as educational level increases. Analogous findings were reported by Glasgow (1997) and by Taft *et al.* (2004) for Swedish population using the SF-36.

PART VII: Conclusion

Chapter 15: Concluding remarks

This study examined the Quality of Life of people with diabetes in Greece. It aimed to increase the knowledge of the impact of diabetes on QoL. For decades now it has been accepted that QoL has to be assessed because should be at the forefront in policy decisions about health care (Williams, 1988).

Chapter 15 summarises the main points of the research, recalls the aims and objectives of the project and relates them to the results. Conclusions emerge as end-results of these relations and recommendations are formulated according to these conclusions. Strengths and weaknesses (limitations) of this project are also highlighted at the end of the chapter.

Two distinct concepts, namely Quality of Life and Health Status, were assessed in this investigation. This study is the first attempt to assess QoL of the Greek diabetes population, therefore there are not any results to be compared with my findings and almost all findings might be considered as a contribution to literature.

Health status (HS) was assessed with a generic health status instrument, the SF-36v2 that measures eight domains of life and produces two physical and mental health summary scores. Some of the findings for the Greek diabetes population were analogous to the ones previously reported by other investigators at the international level. However, two findings constitute important deviations from the general trend.

The first finding, that is new in literature, is that the impact of diabetes in perceived health status, as expressed by the SF-36 component summaries, was greater for mental than physical health. This contradicts previous investigations (Chittleborough *et al.*, 2006; Graham *et al.*, 2007; Schunk *et al.*, 2012), and most importantly it contradicts the diabetes-specific norms of the SF-36, which is used as a reference size in the instrument's manual (Ware *et al.*, 2007).

Two reasons might be invoked for this disparity and justify the finding of this research: the first one concerns diabetes population as a whole and the second refers to the Greek people with diabetes. First, for a long time since onset diabetes has not

any severe effect on physical domains, such physical functioning, role physical or bodily pain and consequently does not affect the physical component summary of the SF-36, which deteriorates gradually. Mental health on the other hand is influenced immediately after diagnosis and continues throughout the course of the disease. In this sense the finding of this research does not seem to be irrational, and probably is more logical than the general view, as the impact on mental health concerns the whole of the sample, while the physical components are not influenced for all the people with diabetes, but only those with medium or high duration.

Another explanation of this finding might be some confounding factors outside diabetes, such as the economic crisis, which started in 2008 and brought about some sort of collective depression in Greek society. Anxiety and uncertainty about the future is widespread among people with diabetes, more than any other period in recent history, mainly because incomes fall drastically, social security coverage is rapidly reduced, and hospitals reduce services due to budget cuts.

The second result that is not in line with previously published results is the impact of myocardial infarction on health status, which is very low compared with other complications. This finding is not isolated but it is in conjunction with the ADDQoL-Gr result, thus it needs some further investigation as there is no obvious explanation for it.

The use of the SF-36 was in some respect an auxiliary one because as a generic measure does not capture diabetes-related issues as the ADDQoL-Gr did (e.g. freedom to eat, employment, sex life etc.). The information elicited from the disease specific instrument was more focused and detailed.

Quality of Life was examined with the use of a disease specific measure, namely the ADDQoL-Gr that assesses how 19 domains of life are influenced by diabetes. The ADDQoL-Gr was translated from the English original and was culturally adopted and validated in order to be used in this project. The new instrument was accepted by the original developer as well as the International Harmonisation meeting of the MAPI Institute held in Lyon-France in 2009 as equivalent to the

original ADDQoL. Copyright of the ADDQoL-Gr is owned by Prof Clare Bradley of Royal Holloway University of London, Egham, Surrey, TW20 0EX, England.

The ADDQoL-Gr is a reliable and easily administered instrument that can be used at both individual and macro levels. Used at the individual level it can provide information about the impact that diabetes and its treatment has on patient's overall QoL. This information covers areas beyond the usual clinical and medical practice and contributes to the concept of personalisation that is much needed in all health services, especially by the Greek one. Personalised care is necessary for all patients with chronic conditions, in order for them to become more involved in treatments and take responsibility for self-care (DH, 2008). The individual has to be treated as someone with his/her own preferences, strengths, motivations and aspirations. In trying to change to the new approach of personalised care clinicians need the tools for identifying the individual perceptions about QoL. The ADDQoL-Gr allows clinicians to follow an individualised approach to treatment and clinical practice and shift from "doing to" to "doing with" the patient. It can also be a valuable tool to monitor changes following an intervention (e.g. change in diet or treatment regimen).

At the macro level the ADDQoL-Gr might be of great help for decision makers in case they decide that they should create a diabetes-management program at a national level and perhaps reduce the total cost of diabetes. It is valid, reliable, and the only existing instrument to be used for the QoL assessment of a population that constitutes almost the 7.5% of the total Greek population.

The number of respondents, the excellent response rate, although not exactly reported, combined with the high number of testing sites gave the opportunity to have a good sample of the Greek diabetes population. Different subgroups formed according to demographic or diabetes characteristics (e.g. income, age, disease duration or education) were examined and compared.

Reliability, in the form of internal consistency, was proved by a high Cronbach's α of 0.915 and almost equivalent item-total correlations. Various forms of validity were assessed including construct, discriminant, criterion, and discriminative (known groups), face, and content validity. Future research should focus on

responsiveness. The establishment of this property would allow clinicians and health planners to measure treatment effects, improving outcomes and quality of care.

The findings of this study add to the literature on the so-called predictors of diabetes dependent QoL in general. At the national level it creates a basis for the almost non-existing QoL literature of Greek diabetes population. The information elicited could be useful for the understanding of the QoL predictors for diabetes patients in Greece. In this sense, the findings of this research might fill an existing gap in the area of diabetes-dependent quality of life. This in turn could be proved of great help at the micro level for clinicians in the treatment decision process. By focusing care and treatment efforts on the areas that have a grave impact on QoL, health professionals not only affect lives of individuals, but at the macro level they provide help to health authorities for redesigning and restructuring the diabetes services.

As expected, the results showed that, with the exception of 4 out of 1027, the patients reported a negative impact of diabetes on their QoL. The most profound effect on diabetes patient's QoL have the restrictions imposed on "freedom to eat", followed by "worries about the future" and "work".

It was also shown that "people's reaction" to diabetes has an almost non-existent effect on QoL, insinuating that people with diabetes are not stigmatised anymore by Greek society. The stigma of diabetes is not uncommon even in contemporary developed societies. "People's reaction" and the irritation caused are very significant for people with diabetes and it is the second, after fear, most common emotion among white Americans (DeCoster, 2003). Stigmatisation of diabetes is important because it undermines the "control", that is the discipline needed for such a demanding treatment, and this in turn leads to further deterioration of QoL (Broom and Whittaker, 2004). It should be noted that "people's reaction" does not refer to stigma only. It is also the overall irritation (annoyance, bother, displeasure) that patients experience from interactions with significant to him/her people (e.g. family).

An interesting finding of this research, uncommon in international literature, where men appear to report higher scores both in health status and QoL, is that in this research males reported a slightly greater impact of diabetes on their QoL. Although

the difference is not statistically significant the result is against the general pattern seen in literature, where men report significantly better results than women. This unexpected result was investigated further and, after taking into consideration other factors such as age or type of diabetes, it was revealed that age played an important role in QoL perception, and it also affects the two genders in a different mode.

This finding becomes more intriguing when the gender differences in health status were assessed with the SF-36, where men reported better health compared with female patients. This contradiction probably justifies the view expressed by Snoek (2000) who argued that physical health is not a strong predictor of people's subjective well-being. It also seems to justify Bradley's (2001) belief about the importance of differentiating QoL from health status. In this case the different results showed that patients perceive QoL and HS in a different manner.

The study showed that there are no detectable differences in QoL among patients with different type of diabetes. However, Type 1 diabetes is associated with younger age, compared with Type 2, which appears significantly later in an individual's life. It has been proved that age is a significant predictor of QoL and in this respect type of diabetes might be a predictor of QoL, but not in its own capacity.

Diabetes-related complications had the most negative impact on QoL. The nature of each complication as well as its severity affects QoL in a different manner. Contrary to the general belief that macrovascular complications have the greatest impact on QoL the results of this project showed that microvascular complications are the most important predictors of QoL. Erectile dysfunction has among all complications the gravest impact on QoL. This finding needs more future research with male young samples, and probably an immediate response from the health authorities, taking into consideration that there is not a single public diabetes-institution specialising in this field.

The results also showed that the severity of complications had a heavy impact on QoL. People with a severe degree of complication score a very low level of QoL compared with any other diabetes sub-group. The same serious effect is observed with people suffering from two or more complications.

Treatment regimen is a significant factor for diabetes patients' QoL. Results from this research showed that insulin treated patients report lower QoL compared with the ones treated with oral agents and/or diet. This could be attributed to the severity of the disease, which is greater for insulin treated patients, as well as to the increased self-care burdens escorting the insulin treatment (Delahanty *et al.*, 2007).

There is an enormous amount of contradicting reports in literature concerning the ambiguous relationship between glycaemic control and QoL. This study showed that there is a significant effect of the level of Glycosylated Haemoglobin on Quality of Life. The higher the level of HbA_{1c}, the lower the level of QoL. The study did not enter the field of intensive glycaemic control versus standard control strategies, because there is a growing belief that the type of control strategy (intensive or standard) does not affect the QoL (UKPDS, 1999; Gerstein *et al.*, 2008; Anderson *et al.*, 2011), nor it significantly affects the danger of macrovascular complications (Gerstein *et al.* 2008).

Duration of diabetes was apparently related to QoL, with an overall deterioration starting after the onset of diabetes. However, the relationship is not linear. There is a considerable fall on QoL levels during the first 20 years of disease. The fall is accelerated during the next twenty years, with a slight recovery appearing after the 40 years period.

Both measures show that marital status affects significantly the levels of QoL and HS, with single people scoring higher than any other sub-group. This could be attributed to the age factor, as single people are usually of a young age. However, the other three subgroups, married, divorced and widowed, could be considered as belonging to the same or neighbouring age groups. Nevertheless, divorced patients have the lowest mean weighted QoL score and mental health scores of HS, followed by widowed and married people.

Educational level was proved to be an important determinant of QoL as well as HS with university graduates scoring substantially higher than any other education group. Although the mechanisms of the relationship are not adequately understood in the case of diabetes, a disease with high demands on self-management, a high

educational level should be considered as an assist in the multi-parametrical issue of disease management.

Income is another predictor of QoL for diabetes people. QoL is analogous to the level of income. It was found that income has a severe effect both on QOL and HS. Higher incomes were related with higher mean weighted ADDQoL-Gr scores, indicating a better QoL for better-off diabetes patients. It is well known that income and social class are proved in literature as strong predictors of QoL and HS. However, very little is known about the mechanisms that determine this relationship. Various explanations have been given on the subject but none of these is universally accepted (Adler *et al.* 1994; Muhlhauser *et al.* 1998).

Although the mechanisms are not known, the quantification of this relationship in Greece is possible. The economic crisis of the Greek economy with severe income reduction, and the phenomenon of neo-pauperism that society is going through, is an opportunity to quantify this relationship. This is going to be a topic for future research with this assessment used probably as the base-line.

The relationship between income and QoL justifies the popular belief among lay people, which is expressed by the word they still use for diabetes: the “aristocrat-disease”. Discussing with lay people about the meaning of the word, the answer received was that “only wealthy people can be seen having diabetes, as poor diabetics are dead”. This is to a great extent an outdated belief, because the social security system that has been developed in Greece during the last 30 years covers a great part of diabetes expenses. Patients’ participation varies between 0% (insulin for type 1, to 10% for oral medication and 25% for consumables. However, the system does not cover all the consumables needed, especially for type 2 patients, and does not reimburse for any of the so-called diabetes accessories such as socks and shoes. By looking at the co-payments section of the analysis it can be seen that there is a negative correlation between co-payments and QoL, indicating that people who spent more out of pocket money have a lower QoL level.

The issue of co-payments should be re-examined by health authorities, especially the flat coverage granted to all type 2 patients irrespectively of disease gravity. The only

existing coverage differentiation is between the two types of diabetes with type 1 enjoying a wider range of benefits. Ignoring the level of gravity of type 2 patients is not in favour of low income people with a severe degree of diabetes that need high cost of treatment and co-payments. It is well documented that passing on the cost of treatment to the patient finally damages both the health system as well as the patient's health (Menzin *et al.* 2001; Caro *et al.* 2002; Piette *et al.* 2004; Mahoney, 2005; Colombi *et al.* 2008; Menzin *et al.* 2010).

There are differences among the hospitals, but this was expected as the reputation of each hospital attracts to a great extent a certain group of people. However, the results from Salonica, especially the ones from Hippokration, need more investigation because its reputation is similar to Evagelismos and Alexandra of Athens, but report different results. Cultural differences should be taken into consideration, as well as the role of small private diabetes clinics, which probably attract some cases with higher degree of severity.

The lowest QoL was reported by patients in Kavala. This semi-urban/rural area in Northern Greece has one of the newest hospitals in Greece, but the level of diabetes care provided is not up to acceptable standards. There is not diabetes centre in the hospital, but the internal medicine clinic accepts patients one day/week with one internist and a nurse running the outpatient clinic; their dedication seems to be the only *raison d'etre* for the existence of this clinic.

This investigation provided evidence that QoL is influenced by many factors such as the level of glycaemic control, the type and severity of complications, the quality of diabetes-care, patient's participation in treatment costs or even the membership of a diabetes-patient group. The main conclusion drawn from these findings, at a policy level, is that restructuring of the diabetes-care system a necessary condition in order to improve overall QoL of people with diabetes.

The restructuring should aim at two major goals. First, the reorganisation of the diabetes-care services, both geographically and institutionally. The problem of service distribution and consequently diabetes management in Greece is severe.

Service distribution in a country that has over 1200 inhabited islands presents a significant problem.

In almost half of the Greek hospitals there is not any outpatient diabetes-clinic. There are almost 70 hospitals where a diabetes outpatient clinic exists, but it operates one or two days a week. Patients have either to visit a private diabetes clinic or travel to the nearest hospital that has a diabetes clinic. These clinics cost only €5 but offer a limited range of services and one medical professional qualified for diagnosis and treatment of diabetes. There are not any consultants (podiatrists, nephrologists etc.) attached to them in case an individual needs special treatment or diagnosis. Some consultants can only be found in diabetes-centres. There are 17 centres in Greece, 12 in Athens, 3 in Salonica, 1 in Patras, and 1 in Heraklion-Crete.

This pattern of geographical distribution imposes additional costs to treatment and creates numerous barriers to access. A visit, on the other hand, to a private diabetes clinic may impose a cost of €200, including the tests, an expense that is not reimbursed by social security. Previous investigations have shown that cost *per se* constitutes a barrier to health care (Newhouse, 1993; Piette, 2000) and consequently to health (Gilmer *et al.*, 1997; Wagner *et al.*, 2001c).

The second major goal of restructuring concerns the issues of diabetes management and diabetes-education. According to Ellrodt *et al.* (1997) there are at least four components of disease management: an integrated health care delivery system capable of coordinating health care across the continuum; knowledge of the prevention, diagnosis, and treatment of the disease; sophisticated clinical and administrative information systems; and continuous quality improvement methods. None of the above exists in the Greek NHS.

Greece does not have any diabetes management program, despite the fact that such programs have been proved effective in improving QoL and other health outcomes (Ose *et al.*, 2009; Knight *et al.*, 2005;). Diabetes programs include patient education, health professional's education, psychological intervention, dietary education, self-monitoring and telemedicine. Follow-up, self-care, and case management are necessary for an effective disease-management and the confrontation of the disease-

burden. (Norris *et al.*, 2002). However, prevention and management of diabetes are not included in the priority list of the Ministry of Health. A national diabetes programme does not exist, because diabetes is not recognised as health condition that should be separately addressed, and there are no official prevalence or other epidemiological data (e.g. number of amputations).

Lack of such programs in the Greek health system results to situations where people at high risk of complications cannot be identified and have a routine follow-up program, nor people at low risk find support for increasing their self-care abilities. Also, case management for people with complex needs is impossible.

The value of diabetes education is widely recognised. It is considered a necessary precondition for successful self-care and disease management (Roberts, 2006). It is also recognised that self-care reduces visits to health care professionals, hospital stays, and confinement at home because of illness (Fries and McShane, 1998). Diabetes education is a major goal for the International Diabetes Federation (IDF, 2011). The five years campaign (2009-2013) of the IDF is titled “*understand diabetes and take control*”. Without education the IDF argues that:

“... people with diabetes are less prepared to take informed decisions, make behavioural changes, address the psycho-social issues presented by diabetes and, ultimately, may be ill-equipped to manage their diabetes effectively” (IDF, 2009).

This education is not a procedure of memorising information about blood- sugar levels, given at seminars or day-meetings and workshops provided occasionally by a diabetes group or even a health professional; it is a rather lifetime procedure that has to be repeated many times throughout life (Khunti *et al.*, 2012). It helps patients to interrelate diabetes-knowledge with every day’s problems enabling them to make multiple daily choices regarding the management of the disease without help from any health professional (Kirkman *et al.*, 2002; Rutten, 2005; Tessier and Lassmann-Vague, 2007; Jarvis *et al.*, 2010).

Diabetes education in Greece is provided by diabetes-patients groups acting on a local basis assisted by diabetes-professionals, mainly on a voluntary basis, and funded by pharmaceutical or companies specialised in medical equipment and

diabetes accessories. The same companies finance conferences delivering education modules for diabetologists. They are also responsible for screening populations for diabetes (Andriciu, 2009). Both diabetes education-training sessions and screening are based on a rather occasional basis than on a systematic and continuous program and with very limited duration (2-3 days).

Good continuity of care is connected with better outcomes, because diabetes is a chronic disease that needs attention and good management (Wagner *et al.*, 2001a). The structure of the Greek health system does not include any provision for ensuring continuity, because first of all there is no national register for people with diabetes. The organisational support, that the national register would provide, and a computerised tracking system would help continuity and improve patient's adherence to treatment (Kirkman *et al.*, 2002). There is a variety of reasons for the existence of the above deficiencies in the Greek health system that cannot be discussed, as they overstep the jurisdiction of this project.

In conclusion, Quality of Life is probably the most important health outcome because it represents the “*ultimate goal of all health interventions*” (Rubin and Peyrot, 1999). In this respect and in order to make QoL more comprehensible this investigation produced an instrument with proved validity and reliability, accepted by its original developer and international institutions, and tried to shed light to the complex relationships of quality of life domains with demographic, socioeconomic, and medical variables.

Last, there is no doubt that the increase of life expectancy is a major challenge for all health systems. The concepts of quantity and quality should not be used in a disjunctive manner. However, quality and not quantity is the most important issue in life and should be prioritised against all other health outcomes, because according to the phrase attributed to Abraham Lincoln, and endorsed by writers, politicians, geriatric and diabetes associations:

“And in the end, it's not the years in your life that count. It's the life in your years”.

Strengths and Limitations of the study

Strengths of this study could be considered:

- The number of testing sites and their relative importance for the total diabetes population. The biggest hospitals of Greece were included in the testing sites, as well as some of the most important teaching hospitals serving diabetes patients from various parts of Greece. Because of the high cost of diabetes, as a chronic disease, state hospitals attract the majority of diabetes patients.
- The sample size. The final number of 1027 respondents is the highest amongst diabetes-related quality of life studies.
- Whilst no records were kept, it is estimated that less than 5% of the patients did not wish to participate when approached. However, the patients that did not respond, did not refuse participation, but they declared that they belong to groups that were excluded from the study.
- The broad range of variables examined. The ADDQoL-Gr covered 19 domains of quality of life, while the demographic-medical questionnaire contained 18 questions of demographic, socioeconomic, medical and attitudinal nature.
- The use of two of the most highly reliable and valid questionnaires used for the research (ADDQoL-Gr and SF-36).
- The mode of administration. Both the instruments are self-administered and there was no mitigation of this rule. The presence of the researcher did not interfere with the administration, but the task was the provision of information about the research, the encouragement for participation and provide answers to any queries asked. One hospital (Papageorgiou of Salonica) was excluded and in another one (Kavala's new hospital) the research stopped because they did not satisfy the administration criteria.

Limitations of the study include:

- The fact that all medical variables are self-reported. Although diabetes patients usually report their diabetes management in accordance with the real

levels of variables such as glycaemic control (Heisler *et al.*, 2003), this is not confirmed in the study by examination of medical records.

- Despite the fact that the catchment areas of the testing sites account for almost 40% of the total diabetes population in Greece, the sample, because of the sampling method, still cannot be considered as representative.
- The length of the combined questionnaire, 94 questions in total (18+2+19+19+36) and the consent form led some respondents not to answer the SF-36 questionnaire.
- No record was kept of non-respondents in the validation study.
- The cross sectional type of study was sufficient to assess associations between socioeconomic - diabetes variables and QoL, causation cannot be ascribed.

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Appendix A: Review of diabetes-specific QoL instruments

1 Appraisal of Diabetes Scale (ADS)

Background

The **Appraisal of Diabetes Scale (ADS)** was developed in the late 80's to 1990 in the USA, by M. Carey and it was first published in 1991 (Carey *et al.* 1991). Its development was based on previous theory and research regarding appraisal processes. Some items were based and customised to diabetes on an existing instrument concerning depression, the Attribution Questionnaire. There was no patient involvement in the construction of the instrument.

Conceptual and Measurement model

The ADS aims “*to assess a diabetic person's appraisal of his or her disease*” (*ibid.*). According to its developers ADS could be useful as a brief screening instrument for adjustment to diabetes. In this respect ADS can be used to identify patients experiencing, or they are at risk for, dysphoric reactions and non-compliance problems.

It is a single index scale and it consists only of seven items. It is the shortest instrument among the diabetes-specific array of measures. These items concern distress, control (2 items), uncertainty, prediction about the future, and coping and effect on life goals.

Patients respond on a 5-point Likert scale. Scores can range from 7 to 35, with higher scores meaning a greater impact of diabetes.

The ADS was tested at the Syracuse Veterans Administration Medical Centre - Diabetes Clinic with a sample of 200 outpatients, divided into two sub groups. 102 patients were asked to complete a battery of 6 measures, including the ADS, and 98

patients completed the ADS only. The patients were mainly Caucasian (91%), with a mean age of was 58.4 years. 81% of them were married with high school education (M=12.2 years). The mean duration of diabetes was 15 years with 65% of them insulin treatment. Examination of the responses shows the patients rate themselves around the midpoint of the 5-point scale on all items (2.457-3.025).

Principal Component Analysis was performed, which produced a single factor, with an eigenvalue of 2.73, which accounted for 39% of the variance. All items had loadings on this factor between 0.424 and 0.752 (Carey *et al.* 1991), well above the minimum acceptable level of 0.40.

Reliability

Internal Consistency and Test-retest Reliability of the ADS were assessed. Cronbach's alpha was determined to be 0.73, which suggests that ADS is reliable for use, although reliability according to Streiner and Norman (2008) is at the lowest acceptable level. Item-total correlations was found to be in the range of 0.281 – 0.589 well above the boundary of 0.20 (*ibid*).

Test-retest reliability was assessed by retesting the sample of the 98 patients that completed the ADS only, 1 hour after the test on the site (95 participants) and 1 week later, by mailing the questionnaire (77 respondents). Pearson product moment correlations were found to be 0.89 and 0.85 respectively, scores that prove ADS stable over repeated administrations.

Validity and Responsiveness

Convergent validity was determined by testing the hypotheses that the ADS would correlate positively with other situation or dimension-specific measures of negative effect. To this end Pearson product-moment correlations were calculated between the ADS and the other measures used in the study. The measures used were the Psychiatric Symptom Index (PSI), the Perceived Stress Scale (PSS), the Diabetic Daily Hassles Scale (DDHS), the Diabetes Regimen Adherence Questionnaire

(DRAQ-R), the Diabetes Health Belief Questionnaire –Revised (DHBQ-R) and Glycosylated Haemoglobin (HbA_{1c}).

The results of the correlation analyses confirmed the initial hypotheses. According to the authors, a strong relationship was proved between the ADS and the PSI, indicating scores of 0.55 for anxiety, 0.39 for anger and 0.58 for depression. The scores for PSS and DDHS were 0.49 and 0.59 respectively indicating again a strong relationship between the ADS and the two measures. The results of 0.31 and 0.42 for the subscales of severity and susceptibility respectively, indicated a moderate relationship between the ADS and the DHBQ-R. Significantly low levels of correlation were observed between the ADS and DRAQ-R, with a score of 0.17, as well as the HbA_{1c} with a score of 0.18. It should be noted that although the initial hypotheses of the authors about convergent validity were confirmed, there was no reference about the magnitude of the expected correlations. Also, the construct validity of the ADS was not assessed using factor analysis.

Responsiveness

There is no evidence concerning the responsiveness of the scale.

Burden and Acceptability

Completion time is reported to be five minutes or less. According to the authors, most of the patients found it easy to complete and it is understood easily by low education or visually impaired people. It was generally well accepted by patients due to the fact that it inquires about diabetes-related information and it does not enter into psychological issues. It is also easily administered by non-professional staff. The response rate for the third administration (1-week retest) of the instrument was 78.5%.

Alternative forms

None.

Cultural and Language Adaptations

None.

Comments

The ADS is a short and easy to administer instrument for the assessment of a diabetes patient's appraisal of the disease. It has a moderate to good internal consistency and good test-retest reliability.

In a later study, the ADS was used to examine the family environment in relation with glycaemic control and psychological adaptation (Trief *et al.* 1998). According to the authors, the ADS was found to strongly predict both glycaemic control and diabetes-related quality of life, making it a potentially first-line screening instrument.

Nevertheless the measure suffers from certain deficiencies. Also, some of the developers' claims are not supported by facts. The first serious deficiency is that there was no patient involvement during its construction with all the consequences that this might cause to an instrument (discussed in the previous chapter). Thus, although its developers claim that the instrument has face validity they could not claim that content validity has been proved. Moreover, the sample used for the test was far from being representative. It is the only diabetes-specific instrument that used a 100% male sample. Therefore, there is no evidence on the ADS psychometric properties concerning women. Also, there was not any attempt to test the instrument's ability to differentiate among any other known groups.

Undoubtedly the ADS is an easy to complete instrument. The developers claim that the ADS is easily understood even by illiterate people. However, taking into consideration that all males in the sample had high school education this claim cannot be proved.

2 Audit of Diabetes Dependent Quality of Life

Background

The Audit of Diabetes-Dependent Quality of Life (ADDQoL) was developed in the UK by C. Bradley in the second half of the 90's and it was first published in 1999. The content was based on the experience of existing diabetes-specific QoL and generic instruments, patient-centred principles, discussion with health professionals and 12 in-depth interviews with adults attending a diabetes clinic (Bradley *et al.* 1999).

The design of the ADDQoL was influenced by the Schedule for the Evaluation of Individual QoL (SEIQoL), a widely used interview measure for individual QoL (Mc Gee *et al.* 1991). The initial draft was reviewed by the working group that had been established by the British Diabetic Association and the Royal College of Physicians and four patients.

Conceptual and Measurement model

The general concept of ADDQoL is how people with diabetes perceive and rate the impact of the disease on all applicable aspects of life, together with the perceived importance of each domain for their QoL (Bradley and Speight, 2002). The ADDQoL calls people with diabetes to imagine how different life would be if diabetes did not exist. To this end the person with diabetes is called to answer questions on how his/her life would be without diabetes. This is unique compared with all other diabetes-specific instruments, which ask questions about the problems occurring from the disease i.e. its burden, and how these problems interfere with their lives.

The instrument consists of 19 items plus 2 overview items and one open question. The open question refers to diabetes management and complications in general. The first of the two overview items is of a generic nature, concerning the present QoL in

general. The second one concerns the diabetes-dependent QoL of the respondent. These items are included, according to the authors, in order to provide single-item indicators of QoL (Bradley, 2005).

Item generation

Two initial versions of the ADDQoL were produced. One consisted of 12 items plus 2 overview items. The second version consisted of 13 plus the 2 overview items. The additional item concerned food enjoyment. The 13 items include all domains (social, physical and emotional functioning), of life that affect QoL for the better or the worse.

Each question is divided into two parts. The first one is about the patients' perception of a particular aspect of life, and asks patients to rate the impact of diabetes in various domains of their lives. The second one is to rate the importance of each particular domain for their life. This was a breakthrough for QoL questionnaires and the ADDQoL is the only instrument that uses an importance weighting for each item.

The 13 items asked questions about: employment/career opportunities, social life, family relationships, friendships, sex life, sporting, holiday, leisure opportunities, ease of travel, worries about the future, worries about the future, family-close friends, motivation, physical ability, people's reaction, and food enjoyment.

Later, in 2002, the ADDQoL has been used by the DAFNE (Dose Adjustment For Normal Eating) study group in the UK to assess the effect of their structured education program. In this study the ADDQoL was modified including 18 + 2 items (Bradley and Speight, 2002).

The new items were: physical appearance, self-confidence, financial situation, living conditions, freedom to drink. Also, several of the previous question had been modified and rephrased.

The respondents were asked to rate the impact of diabetes, for the condition-specific item, on a 7 point scale ranging from "a great deal better" (-3), to "a great deal worse" (+3). A "non applicable" option was provided for 10 of the 13 items, giving the

freedom to the respondent to answer questions considered to be applicable for his/her case.

The patient was asked to rate the importance of each item for his/her life in a four scale rating (0- not at all important to 3- very important). Impact rating of each item was multiplied by its importance rating providing a score between -9 to +9. Non-applicable domains were ignored in the total score. The total score was estimated by the sum of weighted ratings of applicable domains divided by the number of applicable domains. Total scores vary from -9, which stands for the maximum negative impact of diabetes, to +9, the maximum positive impact of diabetes.

The third version of the instrument, the ADDQoL-19, is a modification of the ADDQoL-18 (Bradley and Speight, 2002), which in turn was modified from the ADDQoL-13 (Bradley *et al.* 1999). The instrument, in its present form, consists of 19 items plus the two overview items. In relation to the previous one, this edition contains one new item about 'close personal relationship' and the item about 'holidays or leisure activities' has been divided into two separate items. There was deletion of the item about enjoyment of food, as it was covered by the item of 'freedom to eat'. Also some simplification of the wording of the instructions has been made, as well as that of some items.

Thus the present form of the instrument includes the following items: leisure activities, working life, ease of travelling, holidays, physical ability, family relationships, social life, personal relationships, sex life, physical appearance, self-confidence, motivation, peoples' reaction, worries about the future, financial situation, living conditions, dependence on others, , freedom to eat, and freedom to drink.

The "non-applicable" option was considered to be a weak point in the analysis and it has been abandoned. Instead there are explicit questions at the beginning of 5 items. The respondents for whom the item is not applicable are guided to proceed straight to the next item, assigning a zero score to the item (Bradley, 2005).

The administration of the ADDQoL for the DAFNE project indicated that the instrument has shown a universally negative impact of diabetes on all 18 life domains. Only a few people used the positive side of the scale and the mean weighted impact scores ranged between -3.6 (freedom to eat – the greatest impact) and -0.9 (society's reaction). Thus, it was considered that 3 different positive response options were unnecessary, and there has been a reduction for the condition-specific impact scales from 3 to 1 (Bradley and Speight, 2002).

The score is estimated for the 19 domain-specific weighted impact, by multiplying the impact rating (-3, -2, -1, 0, +1) with the importance rating (3, 2, 1, 0) to produce scores ranging from -9 to 3.

Sample

The instrument was tested in two sites. The first sample was recruited from an adult out-patient clinic in Cambridge and the other one in Bromley at two open educational meetings for adults with diabetes.

The Cambridge sample consisted of 52 patients, 54% of which males, with mean age 52.38 years, 37.2% of them were on diet-tablet treatment, the mean duration of diabetes was 12.71 years, and the mean age of leaving full-time education 16.98 years.

The Bromley sample consisted of 102 patients, 54% of which males, with a mean age of 61.60 years, 67.5% on a tablet & diet treatment regimen, the mean duration of diabetes was 7.27 years, and the mean age of leaving full time education 16.12 years. This sample, according to the developing team, was a convenience sample, which could not be considered as representative, but the pattern of its responses proved to be similar to the Cambridge one.

Factor generation

Unforced factor analysis with oblique rotation (oblimin), for the 12 item version, produced three factors with eigenvalue greater than one. Many items though, had been loading on more than one with loadings of more than 0.40. Following a forced

one-factor solution, by disallowing the other two, all domains loaded on one factor with satisfactory loadings ranging from 0.45 (sex life) to 0.81(social life). When the 13th item was included, that of food enjoyment, there had been no major changes in the factor structure. In the 2002 study, for the 18 item measure, a forced one-factor analysis of the 18 item ADDQoL was performed which proved all items loading greater than 0.50 (Bradley and Speight, 2002). The two overview items were not included in the factor analysis.

Reliability

Internal consistency of the ADDQoL was measured in the relevant studies by estimating the scale reliability coefficient (Cronbach's alpha). In the original study Cronbach's (α) for the 12-item instrument was a satisfactory 0.84 (Bradley *et al.* 1999). In the later study for the 18-item instrument (α) was 0.92, indicating that the ADDQoL-18 is a highly reliable measure. For the latest 19-item version of the ADDQoL, administered in Singapore in 2006, Cronbach's (α) was even higher at 0.93 (Wee *et al.* 2006).

Similar studies, using translations of the ADDQoL give results very close to the original version. The Malay version of the 18-item measure estimated a Cronbach's (α) 0.94 (Kamarul Imran *et al.* 2007), while in the Portuguese translation of ADDQoL-18 α was 0.89 (Costa *et al.* 2006).

Item-total correlation in the initial test ranged between 0.37 and 0.67, well above the 0.20 limit proposed by Streiner and Norman. In the Malaysian edition of ADDQoL-18, Item-total correlation ranged between 0.52 and 0.78.

Test retest reliability was estimated only in the Malaysian study at a 1-week interval. The Intraclass Correlation Coefficient (ICC) was 0.81 (using the one way ANOVA model), indicating that the ADDQoL-18 is a reliable measure.

Validity and Responsiveness

Validity of the ADDQoL was tested against the two overview items included in the measure. The hypothesis of the developers that the measure would correlate better with the diabetes-dependent QoL item than with the generic one was proved. The mean weighted scores correlation with the diabetes-specific item was 0.47, while that with the generic one 0.31. The correlations fall far shorter than 1.0, indicating that the measure provides information that cannot be elicited by the overview items.

The ADDQoL mean weighted score, correlated strongly with the number of reported complications ($r = -0.21$) and perception of hyperglycaemia ($r = -0.32$), indicating a more negative impact of diabetes for people of those categories. Examining the known groups differences (Type 1 and 2) has been proved that in 12 out of 13 items of the measure the impact of diabetes was greater to insulin dependent patients.

Burden and Acceptability

The ADDQoL was first tested in Cambridge and Bromley. In Cambridge 67 patients were approached and only 32 are referred as participants (47.76%). During the two sessions of the Bromley application 142 were given the questionnaire and 102 participated (71.83%). There is no explanation given by the authors neither for the small size of sample in the first testing site nor for the low rate of acceptability.

Alternative forms

More recently, a 25-domain ADDQOL-Teens has been developed which showed high internal consistency and reliability. It is a measure of perceived impact of diabetes and its treatment on the QOL of teenagers. There were two subscales: a 10-item impact-self subscale (measuring the impact of diabetes and its treatment on the individual) and a 15-item impact-other subscale (measuring impact on interactions

with others and the external world). It may be used for routine clinical monitoring in a context of continuing evaluation (McMillan *et al.* 2004).

Cultural and Language Adaptations

The ADDQoL-19 has been translated into 23 languages and validated in most of them. That makes it by far the most translated diabetes specific instrument followed by DHP and PAID.

These languages are: French (for France and Canada), German, Italian, Polish, Spanish (for Spain, Mexico, and the USA), English (for USA, Australia, Canada, India, and Singapore), Hindi (+for UK), Portuguese for Brazil, Chinese, Cantonese for Hong Kong, Hungarian, Malay, Punjabi (+for UK), and Slovak.

In addition to these languages there are translations of the ADDQOL-18 in Norwegian, Russian, Portuguese and Spanish for Argentina.

Comments

[Because the ADDQoL was chosen as the main instrument for this research and in order to avoid repetition the comments section of the ADDQoL has been deleted and can be seen in the main body of the thesis (8.4.1)].

3 Diabetes Care Profile (DCP)

Background

The Diabetes Care Profile (DCP) was developed in the USA during the first half of the 90's by J. Fitzgerald. The development of DCP was based mainly on an existing instrument, the Diabetes Educational Profile (DEP), which in turn was based on another instrument measuring adherence to a medical treatment namely the Health Belief Model (HBM) (Fitzgerald *et al.* 1996). There was no patient involvement in the construction of the instrument and this could be considered as a major handicap.

Conceptual and Measurement model

It was designed as an instrument aiming to measure the social and psychological factors important in a patient's adjustment to diabetes and its treatment. The authors accept the importance of self-care in the management of diabetes and its role in preventing complications. However, self-care has an impact on quality of life. It has long been established that diabetes regimen is multidimensional and that adherence to one dimension does not necessarily imply adherence to others. They accept Kurtz' view that patients' adherence to diabetes regimen is usually poor, especially when life-style changes are involved. (Kurtz, 1990).

The developers of the DCP believe that the instrument is unique because of its comprehensive coverage of the social and psychological aspects of diabetes and its treatment. The comprehensive coverage refers to the fact that the DCP contains in total 234 items and it is by far the longest diabetes-specific questionnaire. Initially the instrument contained 14 scales (Fitzgerald *et al.* 1996), but later 2 scales were added making a total of 16 (Fitzgerald *et al.* 2000).

The DCP now consists of 16 profile scales totalling 116 questions, as well as items about demographic, medical, socioeconomic information and self-care practices. The scale uses a 5 point Likert scale. The subscale scores are weighted averages and there is no total score with this instrument. The 16 scales with the number of items and the scoring are:

Diabetes Care Profile Scale	No of Items	Scoring	
		Good	Poor
Control problems	19	1	5
Social & personal factors	13	1	5
Positive attitude	5	5	1
Negative attitude	6	1	5
Self-care ability	4	5	1
Importance of care	4	5	1
Self-care adherence	4	5	1
Diet adherence	4	5	1
Medical barriers	8	1	5
Exercise barriers	5	1	5
Monitoring barriers	11	1	5
Understanding management practice	10	5	1
Long-term care benefits	5	5	1
Support needs	6	5	1
Support	6	5	1
Support attitudes	6	5	1
Total	116		

The instrument was initially evaluated in two different studies in Michigan. One was in a community setting and the other one at an academic medical centre.

Samples

Data were collected from 440 respondents. 48 of them (11%) were patients with IDDM. 392 (89%) were patients with NIDDM, 150 of them (34%) using insulin and 242 (55%) not using insulin. Mean age was 61 years and mean duration of diabetes 10 years. 55% of the sample was women and 32% had 13 or more years of education. Patients were asked to fill a DCP form and have a blood test to determine GHb levels.

352 respondents were used for data collection from the second sample (medical centre). 116 of them (33%) were patients with IDDM, 120 (34%) patients with NIDDM using insulin and another 116 (33%) not using insulin. The mean age was 54 years and women accounted for the 60% of the sample. Mean duration of diabetes was 14 years. Patients from this sample were asked to complete the DCP and three other previously validated scales i.e. the Social Provisions Scale, the Centre for Epidemiologic Studies Depression scale (CES-D), and the Happiness and Satisfaction Scale.

The DCP was compared with the SF-36 in a sample of 255 NIDDM patients, 64% of whom did not use insulin. Their mean age was 63.4 years and 55% of them were women. The mean diabetes duration was 8.6 years (Anderson *et al.* 1997).

Another study was conducted later, with a sample of African American and Caucasian people with diabetes. The sample of this study consisted of 672 type 2 diabetes patients that were either African- Americans or Caucasians. Their mean age was 63.1 years, 43.8% of them male, with a mean duration of diabetes of 12.45 years. 52% of them were treated with insulin (Fitzgerald *et al.* 2000).

The last study found in literature was one that assessed the reliability and validity of the DCP among Hispanic veterans in three hospitals in the SW of the USA (Cunningham *et al.* 2005). Although the results of this study are similar to the previous ones, it cannot be considered as sound because of major sampling shortcomings. All of the participants were male, all using insulin, and there was a discrepancy of power between the two groups (Hispanics n=81, Non-Hispanic whites 238).

Factor analysis for cluster identification was used with data obtained from the DEP, the instrument on which the DCP was based.

Reliability

All studies suggest that the reliability of the DCP is in most part satisfactory but not very good in all dimensions. All analyses showed significant differences among the scales creating doubts about the overall reliability of the instrument. In the Fitzgerald *et al.* study (1996) some of the subscales appear to have excellent reliability (long term care benefits 0.95-0.95, importance of care 0.90), others marginally acceptable (negative attitude 0.75-0.77 and medical barriers 0.75), and some even lower than the minimum acceptable level of 0.70 (exercise barriers 0.60 - 0.66, monitoring barriers 0.65).

In the Anderson *et al.* (1997) study Cronbach's (α) ranged between 0.69 and 0.95 with the exception of exercise barriers which had an α of 0.60. Fitzgerald *et al.* (1998) investigated the reliability of the DCP for African Americans and Caucasians. The reliabilities were found to be similar between the two groups ranging from 0.70 to 0.97 for African Americans and 0.68 to 0.96 Caucasians. Thus, compared with other diabetes-specific instruments the DCP cannot be placed among the most reliable ones.

Validity and Responsiveness

The DCP scales were evaluated for construct and concurrent validity. The authors hypothesized that specific DCP scales would correlate with the scales that were used in the academic medical centre, as well as with the GHb levels measured in the community centre sample.

As hypothesized, the Social Provisions Scale was proved to be negatively correlated with the social and personal factors scale (-0.33) of the DCP, and positively correlated with the support attitude scale (0.51) of the instrument. As far as the CES-D was concerned, the authors hypothesized that would correlate with certain scales of the DCP. Positive correlations were expected for control problems, social and

personal factors and negative attitude scales. Negative correlations were expected for self-care ability, support attitudes and positive attitude.

All hypotheses were proved valid and to the right direction. Correlation coefficient of control problems was 0.34, social and personal factors 0.48, negative attitude 0.48, self-care ability -0.42, support attitudes -0.35 and positive attitude -0.53. Obviously, the correlations of these external scales with the DCP were >0.30 , the level that the authors considered as indicative of concurrent validity for the DCP.

The Happiness and Satisfaction Scale was hypothesized to correlate positively with positive attitude, self-care ability and support attitudes and negatively with social and personal factors and negative attitudes. Although the correlations proved to be in the right direction only two, positive attitude (0.32) and self-care ability ((0.30), proved to be of some significance, with all others scoring under 0.30.

Construct validity in the community sample was tested by assessing the DCP scale correlation with the GHb levels. Due to the fact that many different factors affect GHb levels, the authors hypothesized that only moderate correlation (0.20 – 0.50) would occur. Only three scales correlated with GHb, control problems (0.21), self-care ability (-0.33) and self-care adherence (-0.28). These correlations mean that patients facing difficulties with control problems had also high levels of GHb and patients reporting greater self-care ability and adherence had lower levels of GHb. Significant differences were found between type 1 and type 2 diabetes patients for 6 out of the 14 scales of the Fitzgerald *et al.* study (1996).

In the Anderson *et al.* study (*op.cit.*) the DCP was compared with the Short Form 36 (SF36) for NIDDM (type 2) insulin and not insulin user patients. Overall the DCP correlated well with the SF-36 subscales. A greater number of significant correlations were found for patients with NIDDM not using insulin. The Social and Personal Factors subscale of the DCP had the highest number of correlations with the SF-36 subscales. For insulin users this subscale correlated with six SF-36 subscales, and for non-insulin users the subscale correlated with all nine SF-36

subscales. The positive and negative attitude subscales of the DCP correlated with the Mental Health subscales of the SF-36.

The study examined the relationship of the DCP and SF-36 scores to glycaemic control. They found that the SF-36 scales were not predictive of GH_b values, while the DCP scales explained 17% and 15% of the variance in GH_b values for insulin and non-insulin users respectively. The study also examined the relationship of SF-36 and DCP subscales to the number of complications. For insulin users only two DCP scales were correlated with number of complications (Social - Personal Factors and Positive Attitude). For non-insulin users no DCP subscales correlated with complications. For the same group of patients the General Health scale of the SF-36 correlated with number of correlations.

There was no evidence about responsiveness.

Burden and Acceptability

The DCP contains 234 items and it is by far the longest diabetes-specific questionnaire. The completion time is, according to the authors, 30 – 40 minutes. This time seems to be unrealistic as a speed of 8-10 seconds on average per question is not easily achieved for a questionnaire of 234 items length.

Out of 1,017 patients invited to participate in the community study 517 agreed and only 440 responded (43.26%). A lower acceptability is observed in the medical centre. Out of 1500 patients invited, 576 agreed but only 428 participated (28.5%). The acceptability rate is low, by any standards, and this can be attributed to the length of the questionnaire.

Alternative forms

The use of one or more individual subscales represents alternative forms of the DCP.

3.7 Cultural and Language Adaptations

None reported.

Comments

As mentioned above a major shortcoming of the DCP is the non-patient involvement in its development. The length of the DCP is also a serious disadvantage. However, certain subscales can be used and have been used independently. Of course some questions about reliability and validity could be raised by using two three or four out of the sixteen subscales. But even if the problem of the properties of certain subscales could be overcome the problem that could not be ignored is that by using these subscales only some dimensions are tapped and not the concept of quality of life as a whole. Therefore, in its complete form the instrument is difficult to administer and in a short form is unreliable as a quality of life measure.

4 Diabetes Health Profile

Background

The Diabetes Health Profile (DHP) was developed in the UK by K. Meadows and his team between the second half of the 80's and the first half of the 90's. It was first published in 1996 (Meadows *et al.* 1996). The DHP is a multidimensional patient self-completion diabetes-specific instrument designed to identify psychosocial dysfunctioning of adult insulin dependent and insulin requiring patients in an ambulatory care setting. The instrument was developed specifically for IDDM patients (Type 1) and later, in 2000, it was adopted for use with Type 2 patients (*ibid*).

Conceptual and Measurement model

Item generation

The development of the DHP was based on in-depth interviews with 25 insulin dependent and insulin requiring patients, examination of existing instruments, discussions with health care experts, and a literature review.

In the first study, concerning the instrument's development, five areas were identified and used as the underlying constructs for the instrument's development. These were: psychological distress, barriers to activity, eating restraint failure, disease management, and anxiety related to clinic attendance. 95 items were developed to cover these five constructs. The questionnaire was assessed by four health care experts in order to refine the item content, as well as for a provisional estimation of its content validity. They all agreed on the scales and content of the instrument, rewriting a few ambiguous questions.

Item reduction- scale generation

In the second study, the factor structure of the 95 item instrument was examined and the content of the items was evaluated. To this end, a sample of 239 respondents from a hospital's out-patient clinic was used. Their mean age was 40.85 years, and their mean duration of diabetes was 13.7 (*ibid*).

Principal Axis Factoring (PAF) was chosen for the analysis. 24 items failed to satisfy the criteria put by the developers, (i.e. good endorsement at least by a significant minority of respondents, and item inter-correlations under 0.30 and over 0.70 had to be deleted), leaving 71 items for further analysis. To identify the factors that emerged, PAF analysis with orthogonal rotation was carried out with the 71 remaining items. Five factors emerged, similar to the five initially postulated structures, accounting for 35.8 of the total explained variance. However, two of these factors, management and anxiety, accounted for less than 3% of the explained variance and they had to be removed. Thus the 16 items representing these factors had to be excluded, together with another 12 items with factor loadings of less than 0.30. Another PAF analysis was carried out with the 43 remaining items, to

determine the factor structure, resulted to three factors, explaining 33.3 of the total variance.

A third study took place in out-patient clinics of general and teaching hospitals in England and Wales. 84 hospitals were asked to participate in the study, 74 agreed to do so, but only 54 participated in the end 2,239 patients responded to the 43 item questionnaire with 1144 (51%) of them men, and a mean age of 39.8 years and 13.1 mean duration of diabetes (*ibid*).

A forced three factor PAF analysis was carried out which this time proved that the three factors accounted for 31.5% of the total explained variance. 4 items had factor loadings <0.30 and another 7 items had loadings >0.30 on more than one factors. Thus, all 11 items had to be removed leaving the questionnaire with 32 items. These items were again subjected to a forced three factor PAF analysis with orthogonal (varimax) rotation. All items loaded well on their factors, which were identified as Psychological Distress (14 items), Barriers to Activity (13 items) and Disinhibited Eating (5 items). The three factors accounted 33% of the total variance.

The final stage of the instruments development was a fourth study aiming to assess further the factor structure, the reliability and validity of the instrument. 233 patients responded, 121 of them men (52%), with mean age of 51.46 years. The three factor PAF analysis with varimax rotation followed proved that the three factors accounted for 35% of the total explained variance. Although the strength of the factors was somehow different from the previous studies, with BA accounting for most of the explained variance (22.6%), the item composition of the factors was identical (*ibid*).

The DHP after the four phases of development is a 32 item questionnaire addressing 3 dimensions: psychological distress containing 14 items, barriers to activity with 13 items and disinhibited eating with 5 items. Respondents are asked to rate their answers on a 4-point Likert scale. Response categories are 0-3, with 0 representing no dysfunction or impact.

Subsequent Studies

In 1996 the DHP was translated in Dutch and the psychometric properties of the translated instrument were assessed (Goddijn *et al.* 1996). The Dutch version of the DHP, in contrast to the original one, addressed patients with NIDDM.

As a result, instead of 32, the DHP-Dutch contained 31 items due to the omission of the insulin injections item. The Dutch instrument had the same factor structure, but with similar factors. 8 out of the 31 items loaded on different factors. The three factors explained 32% of the total variance.

Reliability

Internal consistency was assessed for the first two samples, and Cronbach's (α) coefficient for the three subscales exceeded the 0.70 barrier. For psychological distress (α) was 0.86, for barriers to activity it was 0.82, and for disinhibited eating 0.77. For the third sample Cronbach's (α) for the three factors were 0.85, 0.85 and 0.80 respectively, values that seem consisted with the ones of the other two samples. In the DHP-Dutch Cronbach's alphas were found lower than the original but still at a satisfactory level. For psychological distress α was 0.72, for barriers to activity it was 0.79, and for disinhibited eating 0.72.

Validity and Responsiveness

Face and content validity

The methods of deriving the items and the consecutive tests for subscale development and factor structure provide satisfactory evidence for face and content validity (Meadows *et al.* 1996).

Construct validity

Convergent and discriminant validity were assessed during the various tests of the instrument.

Convergent validity

It was assessed during the fourth study of the instrument's development. The authors investigated predictions regarding the hypothesised association between the DHP and the Hospital Anxiety and Depression Scale (HAD) and a generic instrument, the SF-36.

The Psychological Distress (PS) scale correlated highly with the anxiety and depression subscale scores of the HAD (0.62 and 0.60 respectively). The PS scale was also highly correlated with various subscales (vitality, social function, mental health and general health perceptions) of the SF-36, with scores 0.55, 0.51, 0.68 and 0.62 respectively. The Barriers to Activity (BA) scale correlated moderately with the HAD anxiety and depression subscales, with correlations of 0.51 and 0.50 respectively. A low to moderate correlation (0.28 and 0.30) was observed between Disinhibited Eating (DE) and the two subscales of the HAD as well as to the four subscales of the SF-36 with scores varying between 0.17 and 0.41.

In the Dutch study, the findings of the initial test results concerning convergent validity were to a great extent confirmed. The PD and BA subscales correlated highly with the corresponding dimensions of the SF-36, showing comparable results with the initial UK study. These subscales correlated also with the other non-corresponding dimensions of the SF-36, although less strongly. The DE subscale did not correlate with the SF-36.

Discriminant validity

During the third study the discriminant validity of the DHP was assessed, by comparing scores between men and women, divided in age sub-categories. The authors predicted that women in general would score higher in all three subscales of the instrument. The results confirmed the predictions for PD and DE subscales, especially for young women. Women younger than 40 years of age scored significantly higher than men in the PD subscale and women younger than 65 scored significantly higher in the DE subscale. As far as the BA subscale was concerned, although women scored higher than men, there was no significant sex difference.

Responsiveness

The responsiveness of the DHP was never formally evaluated. However in a study that took place in the UK, the responsiveness of two scales was assessed (Whitty *et al.* 1997). The scales used were the scales that emerged during the second face of the item reduction process. Thus, the psychological distress scale has 16 items and the barriers to activity 15.

Patients changing from diet/tablet to insulin treatment were measured at baseline, in 6 weeks and in three months. The Standardised Response Mean were 0.23 and 0.02 in 6 weeks, and SRM in 3 months were 0.11 and 0.08 for the two scales respectively. According to the authors, SRM values of 0.2 are considered to be low. Therefore the changes measured for the two scales were low to insignificant, indicating a failure of these two scales to detect changes over time.

Burden and Acceptability

The first 95 item questionnaire was sent to 278 patients and 239 of them returned them, resulting to a response rate of 86%. As far as the second sample (third study) is concerned, due to anonymity and the fact that the study took place in 54 sites, it was not possible to determine its response rate. 83.85% of those who answered the 43 item questionnaire answered all items. A significant association was observed between low item completion rate and increasing age as well as women. 295 questionnaires were distributed for the fourth study. 233 of them were returned, giving a response rate of 79%.

Alternative forms

By the year 2000, the DHP was adapted for use with type 2 diabetes patients, with studies taken place in England and Denmark. Items from the original instrument (DHP-1) relevant to insulin treatment were excluded and a new version emerged, containing 18 items. The psychological distress scale consists of 6 items, barriers to activity 7 items and disinhibited eating 5 items (Meadows *et al.* 2000).

The DHP-18 was tested in two diabetes centres, one in the UK and one in Denmark. Cronbach's (α) for the three scales in both sites ranged between 0.70 – 0.88. The discriminant validity was assessed by distinguishing between insulin and tablet/diet treated patients. The results confirmed the hypothesis that insulin users would have a greater impact compared with no insulin users. Also, the equivalence between the item mean scores of the UK and the Danish samples indicated a high degree of measurement equivalence across both languages. Therefore, according to the authors, the instrument was proved to have good internal consistency, validity and measurement equivalence (*ibid*).

Cultural and Language Adaptations

The DHP has been translated in 14 languages. These languages are Danish, Dutch, English for Australia, English for South Africa, Flemish, French, German, German for Switzerland, Hebrew, Italian, Polish, Russian, Spanish and Urdu (PROQOLID). According to the Mapi Institute all these translations have undergone full linguistic validation.

Comments

The DHP is an instrument focusing on diabetes related distress, activity and eating behaviour for people with type 1 diabetes. Later, in a shorter version the DHP-18, the measure was adopted only for use with type 2 diabetes. In this respect, the DHP is unique because it is the only diabetes type-specific instrument. This feature could be of very important value for clinical studies.

It is one of the most carefully designed and elaborated instrument. The item generation and item reduction procedures are probably the lengthiest among the diabetes-specific instruments. This accredits the DHP with face and content validity. Reliability of the instrument in terms of internal consistency is good. Test-retest reliability was never assessed for the whole instrument, although two of its subscales were tested in another study with satisfactory results (Whitty *et al.* 1997). In the

same test the responsiveness of the DHP was tested with poor results. Last, the DHP was tested for convergent and discriminant validity with very satisfactory results.

Despite the good qualities of the DHP, that make it reliable to use it in a trial, there are certain shortcomings that make it difficult to use it in a survey. The initial version, with 32 items, is a lengthy one, especially if the measure is combined with a generic instrument. Additionally the type-specificity of the instrument makes its use almost impossible for a general surveys, as the results of the two diabetes-type groups in these studies should be comparable.

5 Diabetes Impact Measurement Scales

Background

The Diabetes Impact Measurement Scales (DIMS) was developed by Hammond and Aoki in California USA and it was published in 1992 (Hammond-Aoki, 1992).

Conceptual and Measurement model

The aim of the authors was to develop an evaluative index designed to measure longitudinal change in adult patients with diabetes, in order to quantify treatment benefit in clinical trials. The scale was designed for application to people with type 1 and type 2 diabetes.

The scale consists of 44 items covering 4 domains: symptoms with 17 items (diabetes-specific 6 items and nonspecific symptoms 11 items), well-being with 11 items, diabetes-related morale (i.e. patients' attitudes toward managing the disease) with 11 items, and social role fulfilment with 5 items.

Item generation

The development of the DIMS was based on previous research and studies on health status measurement as well as discussions with clinicians (physicians, diabetes-nurse and dietician). The instruments used were the Sickness Impact Profile (SIP), the

Arthritis Impact Measurement Scales (AIMS) and the Rand Study Scale from which some well-being related articles were directly drawn. There was no patient involvement in the construction of the instrument. The 44 developed items were grouped into four subscales: symptoms specific and less specific to the disease, diabetes related morale pertaining to the management of the disease, social role fulfilment, and well-being.

Item reduction - Factor generation

Principal Component Analysis was used to determine the factor structure of the questionnaire. One principal component was accounting for 32% of the variance and another nine minor components each one accounting for $\leq 7.5\%$ of the variance bringing the total variance explained to 69%. This analysis showed that there is a major factor being measured by all subscales and total-scale scores and several minor factors that for which there was no statistical evidence supporting the unique significance of the subscales i.e. their capability to provide information beyond the ones provided by the total DIMS score.

An item-total correlation analysis was performed proving that four items (16, 22, 39, and 42) did not correlated significantly with the total scale score. Although the authors accept that these items should be deleted from the questionnaire, for reasons that are not clear in the report, they have left the item reduction task to future studies, which have not been found in literature.

Scoring method

Patients respond to items on a 0-4 Likert scale, referring to the frequency of occurrence during the last month (0: all of the time, 4: none). The overall score was calculated by summing-up the item scores in the same scale. High scores represent good values for the domains covered by each subscale (Li *et al.* 2006). Two global questions included in the questionnaire packet, concerning control of diabetes and general health used a 90mm VAS.

Sample

130 patients were recruited from the diabetes clinic of the University of California Medical Centre. Their mean age was 45 years, 55 of them (42%) were men, with a mean duration of diabetes of 11 years. 51 patients (39%) had IDDM and 77 (59%) had NIDDM (2 patients unclassified).

Reliability

Internal consistency of the DIMS was low to moderate. It was estimated by calculating Cronbach's alphas of the subscales. They ranged between 0.60 (specific symptoms) to 0.85 (social role fulfilment scale) and 0.94 for the total score. Correlations of subscale and total-scale scores ranged between 0.46 (social role fulfilment) and 0.97 (non-specific symptoms).

Test-retest reliability was estimated with repeated administrations over a period around one month by 52 respondents out of the 130 of the sample. Correlations ranged from 0.61 for the well-being scale, to 0.78 for the diabetes-related morale.

Validity and Responsiveness

Construct validity of the DIMS was assessed by examining the correlations of the instrument's scores with the global rating scales and the clinical variables. To this end each participant was handed, in addition to the questionnaire, two global rating scales of a 99-mm line (Visual Analogue Scale), where the patient was asked to rate the control of diabetes and his/her general health (physical, mental, emotional). The same scales were presented to clinicians to be completed on behalf of each one of the patients.

The developers hypothesised that higher DIMS scores would be negatively correlated with the clinical variables that indicate the presence of the disease. Most of the DIMS scales showed to be highly correlated with diabetes control and health status in both the patients and clinicians ratings. Correlations between DIMS scales

and control of diabetes ranged between 0.25-0.55 for patient, and 0.24-0.38 for clinicians ratings. Correlations between DIMS scales and general health ranged between 0.27-0.47 for patient, and 0.29-0.45 for clinician rating.

Correlations between 38 clinical variables (diabetes type, duration of disease), and DIMS scales varied, but they were generally of low magnitude, with the exception of HbA_{1c}, which showed some significant correlation with the symptoms and well-being subscales. Diabetes complications were not significantly correlated with DIMS scores. The presence of retinopathy, nephropathy, gastropathy and numerous other variables showed no significant correlations with DIMS.

Demographic variables such as age and sex were found to be significantly correlated with DIMS scale scores. Age was positively correlated with well-being and morale subscales. Sex was strongly correlated to the symptoms, well-being and morale subscales, with females scoring lower. Social role fulfilment scale was not strongly correlated, although it was in the same direction. There was a strong negative correlation between DIMS total score and sex.

The **responsiveness** of the DIMS was never assessed.

Burden and Acceptability

The authors report a 15-20 minutes completion time. The scale is designed for completion by people with sixth-grade reading ability.

There are not any details about the percentage of the patients who responded to the test, but only the fact that 90 patients (69.2%) answered all the questions of the DIMS. The omissions according to the authors were due either to oversight or because some items were not applicable to the respondents, which seems to be nearer to reality.

Alternative forms

None.

Cultural and Language Adaptations

The 44 item DIMS was translated into Chinese and its reliability and validity was assessed for 219 patients with type 2 diabetes at a teaching hospital in Taiwan. The mean age of the participants was 63.5 years, 35% of them males, with a mean duration of diabetes 8 years (Li et al. 2006). Internal validity of the Chinese version was estimated with α coefficients ranging between 0.61 (morale) to 0.78 (symptoms) and 0.86 (total score). The results are not satisfactory, they are below the ones of the original validation with three out of the four scales scoring less than 0.70. The translators blame the small sample size and the low level of literacy for the poor results. Test-retest coefficients are given as ranging between 0.55 and 0.92, but the measurement concerns only 20 patients with unclear time intervals. For the construct validation of the instrument the team hypothesised that patients with complications, poor glucose control and co-morbidities would have lower DIMS scores. All hypotheses were confirmed by the test results. The DIMS has also been translated and validated into French by Mapi Institute and there is also a translation in Italian (Proqolid).

Comments

The authors conclude that the DIMS is a valid measure of health status and disease impact. They claim that the significant correlations are in the directions they expected. Out of the 266 correlations examined, (7 scales and 38 clinical variables), 57 of them were above the expected level.

However there are some structural problems with the DIMS. First, there was no patient involvement in the initial phase of the DIMS's development, with all the deficiencies that this might cause to an instrument. Second, the developers do not seem to pay particular attention to the fact that clinical variables and complications, variables that one should expect to have an impact on health status and well-being, show only insignificant negative correlations with the DIMS scores. This is against their initial hypotheses as well as the prevalent opinion among researchers (Rubin

and Peyrot, 1999), but the developers do not value it in their conclusions. Third, the authors do not give a satisfactory explanation why although the item reduction and scale generation process showed some interesting results related to the poor performance of some items and subscales, casting doubts about the value of information provided as well for their existence as such, they did not proceed to solve the problem, leaving it for future studies. Thus, the structure of the DIMS has to be reconsidered before it can be seen as a reliable instrument. Finally, comparison of responses to the DIMS of people with and without diabetes and the changes occurring to the scores due to a therapeutic intervention, was also postponed for future studies.

6 Diabetes Quality of Life Measure (DQOL)

Background

It is the first diabetes-specific instrument ever created and it remains one of the most widely used. Diabetes Quality of Life Measure was developed in the USA in the first half of the 1980s. It was first introduced in 1988.

The new instrument was designed for adults and adolescents with type 1 diabetes, to be used within a controlled randomised clinical trial (Diabetes Control and Complications Trial). The trial compared the efficacy of two alternative treatment regimens on complications of Insulin Dependent Diabetes Mellitus (IDDM) (Jacobson *et al.* 1988). The measure was later used for QoL evaluation of Non Insulin Dependent Diabetes Mellitus (NIDDM) (Jacobson *et al.* 1994).

Conceptual and Measurement model

The objective of the instrument initially was to evaluate the burden of an intensive diabetes treatment regimen (Jacobson, 1994). The goal of this treatment was to

achieve blood glucose levels near to the level of people without diabetes. The idea was that intensive treatment would have effects on patients' QoL and by measuring the patients' personal experience a measure of QoL would occur.

The scale contains 46 core items and deals with four dimensions of QoL. The first one is satisfaction with treatment, containing 15 core items plus three additional items addressed to adolescents. The second dimension refers to the impact of treatment, containing 20 core items, and 7 adolescent-oriented optional items. The third and fourth dimensions, containing 11 core items, deal with worry about complications of diabetes in the long run (4 items) as well as worry with social/vocational concerns (7 items) and 3 adolescent-oriented optional items.

Item generation

The items were derived initially by reviewing the literature on psychosocial aspects of diabetes and confirmed by type 1 diabetes patient and clinicians' consultations. The instrument has been reviewed and revised by its developers many times and substantial changes took place throughout this procedure. During these revisions the worry dimension was added as well as the scoring method was changed.

No further details were reported for the item generation process, except the authors' claim that the strategy for scale development followed was similar to the one recommended by Guyatt *et al.* (1986).

Item reduction/Factor generation

There is no report by the developers on any formal use of Factor Analysis either for item reduction or factor generation of the measure. The only relevant reference found in literature was an informal assessment in a study published in 1992. In this study the DQOL was used as a measure to assess the QoL in young adults with type 1 diabetes in relation to demographic and disease variables. In this study the 46 items of the DQOL were submitted to a Principal Component Analysis with varimax rotation. This PCA was followed by another two analyses of individual subscales (Eiser *et al.* 1992). The PCA combined with the FAs did not confirm the four subscale structure proposed by the Jacobson team. Their analyses resulted in three

subscales: impact/worry, social relationships and diabetes concerns. However, this study could not be considered reliable as the data used were from a sample of 69 patients only, which is too small for an instrument of 46 items.

Scoring method

Patients have to respond to items on a 5-point Likert scale. Initially, as the score increased the situation was considered as deteriorating. Thus, satisfaction rated from very satisfied (1) to very dissatisfied (5), situations concerning the impact and worry vary from never (1) to all the time affected or worried (5). The scores were presented as the total of the items of each dimension divided by the number of items. A low score indicated good QoL and conversely high scores indicated a bad one. Later the method of scoring changed, because it was considered to be not user-friendly (Jacobson *et al.* 1994). The responses since, have been reverse - scored i.e. positive QoL is getting a higher score. The scores are then summed up into a 100 point scale, where 0 represents the lowest possible level of QoL and 100 the highest. The raw scores are converted to 0-100 point scale according to the SF-36 formula (Jacobson, 1994).

Sample of DCCT study

The sample of the initial development of the DQOL was randomly selected from the 21 diabetes centres participating in the DCCT project. 192 responded, 136 (70.8%) of whom were adults and 56 (29.1%) adolescents. 190 patients completed fully the questionnaire, the mean age of the adults was 28 years. 114 were men (60%) and 76 women (40%). The mean duration of diabetes was 8 years. 40% of the adults were married.

Subsequent studies

The Parkerson *et al.* study

A study, aiming to compare a disease specific instrument, the DQoL, with two generic measures, namely the Duke Health Profile (DUKE) and the General Health Perceptions Questionnaire (GHP), was published in 1993 (Parkerson *et al.* 1993). The sample for this project consisted of 170 patients with a mean age of 33.7 years,

46.5% of them men, 78.6% had at least high education, 63.9% were married and the mean duration of diabetes was 15.6 years.

The Jacobson *et al.* study

As already has been mentioned, in 1994 the Jacobson's team (*op.cit*) published the results of another study for DQOL Measure. This time the study concerned adults only, 18-80 years of age. According to the authors, the aim of the project was to examine the effects of type I and type II diabetes on patient perceptions of their QoL and compare the psychometric properties of a generic versus a diabetes-specific QoL measure. 5 out of the 6 scales of the SF-36 were used for the comparison.

There was not any elaborated process in order to adapt the IDDM and adult-adolescent oriented initial version of the measure to a NIDDM- adult population. The authors simply decided that respondents would be included only if they had completed 12 out of the 15 satisfaction items, 16 out of 20 impact items, 2 out of 4 diabetes worry items, and 5 out of 7 social/vocational items. The study took place in the out-patient department of a diabetes centre in Boston USA. 240 patients participated, 111 of whom with type I diabetes (46.25%) and 129 with NIDDM (53.75%). The mean age of type I diabetes patients was 44 years, 52 of them (47%) were male, 70 were married (63%), 86 (77.5) of them had at least high school education and their mean duration of diabetes was 18.8 years. The 129 type II diabetes patients had a mean age of 60 years, 66 of them (51%) were male, 89 were married (69%), 75 (58%) of them had at least high school education and their mean duration of diabetes was 12 years. Of course, all of type I diabetes patients were treated with insulin, while 68 (53%) of type II were on insulin treatment, 49 (38%) on tablet treatment and 10 (9%) on diet only (*ibid*).

Reliability

Cronbach's α was estimated in the DCCT study ranged between 0.67 and 0.88 for the 4 subscales and 0.92 for the total DQOL. The diabetes related worry scale was the one that failed to reach the 0.70 limit. In the Parkerson *et al.* (1993) study alphas were lower than the DCCT's study, ranging from 0.52 (diabetes-worry) to 0.88 for

the total DQOL. In the 1994 Jacobson *et al.* study (*op.cit.*), Cronbach's α coefficients ranged between 0.47 and 0.87. In all three studies it is obvious that internal consistency of the diabetes-worry scale is not at a satisfactory level.

Test-retest reliability showed that the DQOL is a fairly stable instrument. It was assessed in the DCCT study with a mean interval between the two administrations of 9 days and a median of 7 days. Pearson product-moment correlations for adults were estimated between 0.78 (social/vocational worry) and 0.90 (for the total DQOL).

Validity and Responsiveness

Content and face validity

The procedures followed in the item generation stage of the instrument's development that have been mentioned in the relevant section above, advocate for a good face and content validity, but for type 1 patients only, who participated in the development procedure.

Construct validity

In the DCCT study the relationship of the DQOL was examined against three measures, namely the Symptoms Checklist 90-R (SCL-90), the Bradburn Affect Balance Scale (ABS) and the Psychological Adjustment to Illness Scale (PAIS). The authors expected significant positive correlations, especially with the total DQOL. The anticipated correlation range was 0.30 to 0.70.

Moderate to strong correlations were between the DQOL and each of the three measures. Correlations between the DDQOL and the SCL-90 were ranging between 0.40 (diabetes worries) and 0.60 (DQOL total). The ABS also showed the same pattern of positive relationship with the ABS coefficients ranging between 0.27 (worries) and 0.57 (DQOL total). Similar, although lower, patterns of correlation were found between the DQOL and PAIS. The DQOL total was almost at the same level with the other two measures, but the worries scales (diabetes and

social/vocational) showed insignificant correlations with some of the PAIS scales (0.6-0.12). The results show that the initial assumptions of the authors were confirmed and prove that the Diabetes Quality of Life is related to psychological well-being, affective balance and adjustment to illness, supporting the instrument's convergent validity.

In the 1994 study (Jacobson *et al.*) construct validity was examined against the Medical Outcome Study Health Survey 36-item Short Form (SF-36). 5 dimensions of the SF-36 were used namely physical, social and role functioning, pain and general health perception. The levels of correlations followed the patterns of the previous study, although at a significantly lower level. The impact and satisfaction scales of the DQOL measure showed the highest correlations with all dimensions of the SF-36 (0.59-social functioning to 0.28-pain), while the worry scales reached statistically insignificant levels.

The authors claim that demographic factors such as sex and education or even the duration of diabetes, are not predictors of QoL. Marital status affects the level of QoL with divorced or separated patients experiencing worse QoL than married ones. Diabetes complications was the strongest predictor of quality of life as a whole, with lower levels of satisfaction and greater impact among patients with more severe ones. Finally, treatment type influenced the diabetes related QoL. Patients on insulin reported the lowest levels of satisfaction and the greatest diabetes impact compared with those on tablet and/or diet patients.

In the Parkerson study the DQOL measure was examined against three generic measures namely the Duke Health Profile (DUHP), the General Health Perceptions Questionnaire (GHP), and the Health and Daily Living Form (HDL). In a Stepwise multiple Regression Analysis, comparing the overall scores of three instruments, the DQOL, DUHP and GHP, the total DQOL had 28% of its variance explained by 1 co morbidity and 3 psychosocial factors, while the DUHP and GHP explained the 29% and 16% of the variance respectively.

In the same analysis, selected subscales of the same three instruments were compared. In the DQOL measure, the social/vocational worry subscale explained 41% of the variance. The variance explained for the other subscales were low to insignificant (21% of diabetes worry, 12% of impact and 14% of the satisfaction subscale). In DUHP the mental health subscale had the highest explained variance (30%).

Last, and probably the most important part of the Parkerson study, was an unexpected conclusion that occurred in the end of the study. The Parkerson's team modified the DQOL into sub-measures, one with the pure disease specific scales of the instrument and one with the pure generic scales. The investigators predicted that disease-specific scores would be more responsive in terms of variance explained by indicators of that disease than the scores of the generic subscales.

Contrary to this prediction, the result of the analysis was disappointing for the disease-specific scales. The variance explained by the independent variables for each of the generic scales was greater than for its disease-specific counterpart. This result, combined with the poor performance of the DQOL relatively to the other two generic measures, led the team not only to believe to that there was not any advantage by using the diabetes-specific DQOL measure rather than generic measures, but also to cast doubts upon the value of disease-specific measures as a whole against the generic ones.

None of the studies supports the discriminant validity of the instrument. On the contrary in some cases the opposite has been indicated. In 1996, a cohort study was published by the Diabetes Control and Complication Trial Research Group concerning the influence of intensive diabetes treatment on QoL outcomes (DCCT 1996). In this study 1,141 (711 on intensive, 730 on conventional treatment) patients with type 1 diabetes participated for periods ranging from 3 to 9 (mean of 6.5 years). The DQOL failed to discriminate between the two treatment regimens. This unexpected result seemed to have created some doubts to the Group about the power of the instrument to detect clinically meaningful changes in QoL. However, the idea

was rejected putting the blame for this failure on a probable inadequate power of the DQOL to detect a relationship between hypoglycaemia and QoL.

This view has not convinced other writers. A few years later the developers of another scale, the Diabetes Specific Quality of life Scale, expressed serious doubts about the discriminant validity as well as the sensitivity of the DQOL (Bott *et al.* 1998). They argued that the measure was not sufficiently sensitive to group differences in order to detect clinically meaningful differences in QoL of patients undergoing intensive diabetes treatment compared with conventionally treated people. Bradley (2001), on the same subject, in a letter to the Lancet argued that this failure of the DQOL:

“...probably had more to do with injudicious totalling of the many varied items, which were all given equal weight (irrespective of relevance or importance to individual respondents) than to any real lack of impact of intensified treatment on QoL”.

Responsiveness

The responsiveness of the DQOL was never formally assessed by its developers. There is an indirect assessment of the four DQOL subscales, when it was used as a constituent of another measure, the Diabetes Quality of Life Clinical Trial Questionnaire (Shen *et al.* 1999). After 6 months of insulin treatment of 328 patients 256 (78%) of them showed an improvement in metabolic control, while 72 (22%) of them deteriorated in their HbA_{1c} measurements. The results do not show a satisfactory level of responsiveness. For the improved group there was a significant improvement relatively to the baseline scores for the satisfaction subscale only (3.8). For the worsened group there was not any significant difference from baseline, with a highest score of 2.4 for the diabetes worry domain.

Burden -Acceptability

Completion time of the QQOL was not reported by the developers. Vague references are only made on the “ease of administration” and “easy to use” items (Jacobson *et al.* 1988; 1994). However, bearing in mind that the later developed 15-item short

form of DQOL was reported as having 10 minutes completion time (Burroughs *et al.* 2004), it can be concluded that completion time could not be less than 25 minutes.

In the initial study 192 patients out of 210 approached accepted to participate in the study (91.4%). The acceptability rate in the second Jacobson study was 88%. In the Parkerson study out of the 170 patients participating in the study, 131 responded to the DQOL, a rate of 77%.

Alternative forms

In 2004 a short form of DQOL was published. It was the Diabetes Quality of Life Brief Clinical Inventory. This version was a 15-item questionnaire focused on diabetes treatment. The aim of the DQOL-15 was:

“To provide an instrument for use in routine office visits, with specific actionable items to improve provider-patient communication, treatment compliance, and health care satisfaction” (Burroughs *et al.* 2004).

The team mailed an initial version of DQOL (60 items), together with an 8 item demographic questionnaire, to 1080 adults with type 1 and 2 diabetes. 498 of them responded, giving a participation rate of 48%. The mean age of the respondents was 51 years, with a mean duration of diabetes 8 years, 47% of them were male, 32% had diabetes type 1, and 41% had high school education.

The reliability and validity of the data were compared with the ones of the Jacobson's study, finding comparable results. Then, they selected 26 items predictive of health care and satisfaction with diabetes control and they used Principal Component Analysis (PCA) to identify items with overlapping content. For type 1 diabetes, six items were identified as predictors of satisfaction with diabetes control and another nine items as predictors of self-care adherence. For type 2 diabetes, six items were identified as predictors of satisfaction with diabetes control and another six items as predictors of self-care adherence.

A regression analysis followed to compare the 6 and 9-item models compared with the initial 60-item model. The results for the type 1 diabetes patients was that the

short models were as effective in predicting overall satisfaction with diabetes control and self-care adherence, as the initial 60-item measure. The results were similar for the 6-item type 2 diabetes models with the initial 60-item model performing slightly better only with self-care behaviours. The models were combined into a 15-item questionnaire, the DQOL Short-Form Clinical Inventory.

The reliability of the inventory, in the form of internal consistency, was good (Cronbach's $\alpha = 0.85$). The short-form correlated strongly with the total DQOL, as well as with its subscales. It was also able to explain as much variance for satisfaction and self-care as the initial version of the instrument. According to the authors, these results show that very little information is lost by the administration of the short-form, compared with the one of the initial measure, with obvious advantages concerning its use in clinical practice.

Cultural and Language Adaptations

In 1996 the DQOL measure was translated into Spanish. The Spanish version consists of 46 items, and the authors claim that it achieved a high internal consistency ($\alpha: 0.90$). Also, this version had some outcome similarities with the original i.e. more favourable scores among younger patients and adult male respondents (Reviriego *et al.* 1996). They concluded that this may be a useful tool to evaluate the quality of life in Spanish speaking patients with diabetes.

The first Chinese version of DQOL appeared in S. Francisco USA, the largest Chinese community of the world outside China, in 1997. This version was used in a study examining the QoL and social environment of Chinese immigrants with NIDDM (Rankin *et al.* 1997). The developers reported good reliability of the instrument with reliability coefficients of the various subscales ranging between 0.85 and 0.95. The sample of the study though was only 30 patients, thus no reliable conclusion could be reached.

Another Chinese version of the DQOL measure that could be used for elderly Chinese immigrants with type 2 diabetes was developed in 1999 in Toronto-Canada

(Cheng *et al.* 1999). This was achieved by modifying and translating the DQOL measure. The forward and backward translation procedure was followed and the translation was reviewed independently by four individuals. The modified Chinese version consists of 42 items and 3 scales, which includes satisfaction, impact of diabetes and related worries. The scale was tested for reliability, with a sample of 70 patients, by evaluating internal consistency (Cronbach's α : 0.76-0.92) and test-retest reliability (Pearson correlation: 0.94-0.99). The authors concluded that the results of their study indicated that this tool was a reliable and valid tool that could be used for elderly Chinese people with type 2 diabetes.

In 2008 a Turkish version of the HRQOL was published (Akinci *et al.* 2008). This version consists of 45 items and four dimensions of QoL. The authors examined the association of socio-demographic and clinical characteristics with quality of life. No details are given about the translation process, as well as any psychometric properties of the measure.

Comments

According to various sources in literature the DQOL is the most widely used diabetes-specific measure (Magwood *et al.* 2008). This could be explained by the fact that it was the first instrument that appeared in the field. It could also be explained by the fact that the DQOL is probably the measure that has been tested for its validity probably more than any other measure. The developers of the DQOL measure claim that it could be useful as part of a battery of measures selected to identify general and disease-specific concerns of people with diabetes. Also, it can be used on its own as a screening measure in clinical settings to detect patients stated or unstated concerns about their disease.

However, the DQOL was designed initially for use with young insulin users (Type 1). When the measure was adopted to type 2 diabetes patients its performance was not satisfactory and its psychometric properties significantly lower. Moreover, a scrupulous review of the items shows that, although the DQOL is a disease specific

instrument, many items do not seem to be strictly and directly connected to diabetes, and could be the result of a broader spectrum of diseases. Among the 15 items of the satisfaction dimension at least 7 can get responses that indicate a burdened condition which might not be the result of diabetes (items 8, 9, 10, 11, 12, 14, 15). The same happens with impact items (6, 8) and the first seven items of the worry dimension. In this respect, and to some extent, DQOL acts as a generic measure.

This view could be considered simply as a value judgement, not having an immediate effect on the relative value of the DQOL. However, the Parkerson's team (see earlier) extended the matter even further, arguing that there is no advantage in the use of DQOL compared with a generic measure. The authors claim that the generic instruments they examined provided as much or even more information about QoL and its relationships with diabetic and non-diabetic factors, as the DQOL measure. This is a very important argument because in its essence invalidates the very nature of the DQOL as a diabetes-specific measure.

The measure has not been thoroughly examined for its factor structure. There is not any reliable reference about using factor analysis for assessing the dimensionality of the DQOL. Doubts about the structure of the DQOL measure have been casted as early as 1994 when Bradley, although she accommodates in her book a chapter written by the main author of DQOL Jacobson and his associates, she points out the lack of empirical evidence concerning the structure of the measure (Bradley, 1994). The only study that performed FA to assess the structure of the DQOL, as it has been accepted, was unreliable due to the small sample size. Nevertheless, the study casts doubts on the structure of the DQOL that the developers did not try to clarify in their subsequent studies. It could be an oversimplification to put the blame for all the above discrepancies upon this omission, but factor analysis would probably be of some help to improve the measure. This view is supported by the findings of the Burroughs *et al.* study (*op.cit.*), where it was proved that the 15-item Brief Clinical Inventory had the same predictive value with the original measure.

Another shortcoming of the DQOL could be considered the fact that although it was created specifically for clinical trials of insulin treated patients its discriminant validity has been seriously disputed and its responsiveness has not been proved. Also, the DQOL is a lengthy instrument, lacking of good evidence that its length is necessary to serve its purpose. However, despite the fact that it is a widely used instrument no attempt has been made to give some convincing answer to all these criticisms.

7 Diabetes Quality of Life Clinical Trial Questionnaire

Background

The development of the Diabetes Quality of Life Clinical Trial Questionnaire (DQLCTQ) started in 1993. The early development stages took place in the USA and France and later stages of the study proliferated to Canada and Germany. In this respect it the only instrument developed on a multinational basis. Another ‘novelty’ of the instrument was the publication of a study that used the DQLCTQ two years before its development and validation were published (Kotsanos *et al.* 1997). The results of the whole study were reported in 1999 by Shen *et al.* (1999). This publication contained a revised version of the instrument the DQLCTQ-R.

Conceptual and Measurement model

The aim of the authors was to develop and validate a questionnaire for use in multinational clinical trials of patients with type I and II diabetes, which would include all health related quality of life domains.

Item generation

The first stage of the study was to identify the domains of importance to patients with diabetes. To do this 30 patient focus groups from San Francisco - USA and Lyon –

France were conducted, 23 of them with type I and 7 with type II diabetes. Additionally, a panel of 11 expert clinicians from the same places gave its views on the subject.

In the second stage a search in literature took place, aiming to identify existing generic and disease specific HRQoL instruments, which contained domains relevant to the ones identified by the patients and clinicians. The questionnaires reviewed included the Diabetes Quality of Life Measure (DQoL), the Questionnaire on Stress in Diabetes, The Hypoglycaemia Fear Survey (HFS), the Health Insurance Experiment, and the Medical Outcome Study (MOS). The developers had to create some new items related to stigma, treatment satisfaction and symptoms, due to lack of relevant domains in the existing instruments. The end-result of this synthesis was a 293- item draft questionnaire.

Item reduction/Scale generation

The draft questionnaire was evaluated for reliability and validity, at 5 clinics and diabetes centres in the USA. 123 patients participated in this pilot study, 51 (41%) of which had type I diabetes and 72 (59%) type II. 58 of the patients completed the questionnaire in a second administration which took place 7-10 days after the first administration. The data were used to assess the test-retest reliability of the draft. Due to the small size of the sample the results of the validation process were not worthy to be reported, but they were taken under consideration for the next stage of the questionnaires' development.

The results of the pilot study, the existing literature, the focus groups, and the experts were used for item reduction, in order to produce an acceptable and practical instrument for use in clinical trials. Redundant items or domains were removed and domains with poor scores in the reliability and validity assessment were eliminated or modified. Two new domains, treatment satisfaction and treatment flexibility were created, aiming to focus on insulin - specific comparisons.

This item-domain reduction process produced a questionnaire, the Diabetes Quality of Life Clinical Trial Questionnaire (DQLCTQ), consisting of 142 items covering 20 domains. 28 items in total were drawn from the generic instruments, i.e. the MOS SF-36 and SF-20 covering General health (1), Comparative health (1), Physical functioning (6), Global role functioning (1), Global difficulty functioning (1), Social functioning (1), General social functioning (1), Energy/fatigue (5), Health distress (6), Mental health (5).

The Diabetes Quality of Life Measure (DQOL) was used to develop 59 items out of the four DQOL domains i.e. Satisfaction (18), Impact (27), Social worry (7) and Diabetes worry (7). 17 Worry items were drawn from Hypoglycaemia Fear Survey (HFS). 31 new items were developed covering treatment satisfaction (3), treatment flexibility (10), social stigma (4), frequency of symptoms (7), and bothersomeness of symptoms (7). Last, 3 self-efficacy and 4 demographic questions were added making a final total of 142 items comprising 34 domains both of generic and diabetes-specific nature.

The instrument was translated into German and French to be used in the multinational clinical trials. The translations followed the forward-backward translation process with in-depth interviews for cultural adaptation. The QQLCTQ was then used in randomised clinical trials in Canada, France, Germany and the USA. Data from the two largest multinational trials were used to evaluate reliability, validity and responsiveness of the questionnaire.

Scoring method

Respondents are asked to score on scales that vary for each domain and range from 1-5 to 1-7 with higher scores indicating better quality of life. A summary score is calculated for each domain, which is the average score for the questions answered, to represent patient's rating. All domains are then converted to a 100-point scale.

The sample

A total of 942 patients from the four countries participated in the two studies. 72 (7.6%) of them were from Canada, 84 (8.9) from France, 188 (20%) from Germany, and 598 (63.5%) from the USA. 468 (49.7) of them had type I diabetes and 474 (50.3%) diabetes type II. 533 (56.6%) of the total sample were males. The mean age for type I patients was 33.8 years and for type II was 58.2. The mean duration of diabetes for the total sample was 12.6 years. Their mean baseline HbA_{1c} was 8.6 (SD =1.6) (Kotsanos *et al.* 1997).

Reliability

Cronbach's α was calculated for all domains of the DQLCTQ. The results demonstrated moderate to high coefficients for all but two domains. Social worry with α : 0.62 and diabetes worry with α : 0.53. The newly developed domains showed good results. Treatment satisfaction: 0.81, treatment flexibility: 0.89, social stigma: 0.84, frequency of symptoms: 0.77 and bothersomeness of symptoms: 0.80.

Test-retest reliability was assessed during the pilot study. The results should not be considered as reliable as the sample was small and a fraction of it, 58 patients, were used during the pilot study. These patients completed the draft version of the questionnaire 7 to 10 days after the baseline. Results are not available for all domains, but for those which produced results ICC were above 0.70 with the exception of diabetes worry (0.56) and social stigma (0.49).

Validity and Responsiveness

Three groups of patients were used to assess the construct validity of the DQLCTQ. Disease-specific and demographic factors were used for the classification. The first group was based on diabetes type, the second one on gender and the third one metabolic control. The hypothesis was that male patients with type I diabetes and

tight metabolic control and good self-perceived control of diabetes would have better metabolic control than any other group.

The results confirmed the initial hypotheses. Patients with good control of diabetes had significantly higher scores in all DQLCTQ domains compared with the ones with low diabetes control. Patients with tight metabolic control appeared to have significantly higher scores in most domains and in only three domains scores were higher but not at a significant level (physical function, social worry and worry HFS). Diabetes type I patients had significantly higher scores in most domains with the exception of four domains where differences were not at a significant level (social worry, worry HFS, treatment satisfaction, treatment flexibility).

A similar mode occurred with gender. Male patients scored significantly higher than females in most domains, with insignificant differences in satisfaction, impact, and social worry. An insignificant but reversed difference occurred in the social stigma domain where women scored higher than men. The social worry domain was the only one that failed to discriminate among the different groups (diabetes type, metabolic control and gender). The worry HFS subscale failed to significantly discriminate between the type of diabetes groups and metabolic control groups. All other domains were able to discriminate at least 3 out of the 4 disease and demographic factors.

Responsiveness

The responsiveness of the DQLCTQ was assessed (Shen *et al.* 1999) with 328 patients after 6 months of insulin treatment. 256 (78%) of them after the six months treatment showed an improvement in metabolic control while 72 (22%) of them deteriorated in their HbA_{1c} measurements. For the improved group there was a significant improvement of the satisfaction and treatment satisfaction domains relatively to the baseline. For the worsened group mental health was significantly worse compared with the baseline. When the differences between the groups are compared, by comparing changes from the baseline, the four domains of health

distress, mental health, satisfaction and treatment satisfaction showed significant changes, indicating good responsiveness to changes of the DQLCTQ.

Alternative forms

The results of the validation that followed the clinical trials were used as the basis for a further reduction of the DQLCTQ. The psychometric properties and the correlation structure between the domains were examined. The result of this process was a short form of the original instrument, the DQLCTQ-R, with 8 domains containing 57 questions. These domains are: Physical function, energy/fatigue, health distress, mental health, satisfaction, treatment satisfaction, treatment flexibility and frequency of symptoms.

All single item domains were excluded from the revised questionnaire. Also both the worry domains of the DQOL as well as the stigma domain were excluded due to low reliability. The HFS worry scale was also deleted because it failed to discriminate between the sub-groups of the sample (diabetes type and metabolic control). The bothersomeness and impact subscales were not included in the revised version due to their high correlations with the frequency of symptoms and satisfaction subscales respectively.

The DQLCTQ-R demonstrated high internal consistency with α s, for the five measured domains, ranging between 0.77 and 0.91. These scores classify the DQLCTQ-R among the most reliable diabetes-specific instruments. Intraclass Correlation Coefficients (ICC) for the same domains ranged between 0.74 and 0.90. The five domains showed that they could discriminate between the patients subgroups i.e. type 1&2 diabetes, male-female, tight-poor metabolic control, and good-poor self perceived control of diabetes.

Burden and Acceptability

The authors claim that the DQLCTQ-R is an easy administered instrument with a completion time of 10 minutes. This claim seems to be very disputable by comparing the revised questionnaire with other similar ones. The short form of DQOL for example, the instrument from which some items of the DQLCTQ are derived, contains only 15 items, and it is reported to have the same completion time of 10 minutes with the 57 item revised version (Burroughs *et al.* 2004).

Cultural and Language Adaptations

The instrument is created for use in clinical trials on multinational settings. Thus, it is the only instrument where translation and adaptation was part of the development process. A German and a French version of the instrument were created before the instrument was even published. Unfortunately, the attempt stopped and since then no other translation has been reported.

Comments

The DQLCTQ is an instrument containing generic as well as diabetes specific items. It is focused on clinical trials and has the advantage of being tested for its psychometric properties under real circumstances i.e. during various clinical trials at a multinational level. According to the authors the DQLCTQ especially in its revised form, could be a reliable, valid and comprehensive instrument in clinical trials. To this end further evaluation and improvement in future studies are necessary.

However, the fact that the development of the DQLCTQ was not the result of primary research should not be ignored. In this respect the DQLCTQ was not an original instrument. It was rather a compilation of already existing generic and disease-specific measures, aiming to provide a tool in clinical trials. This peculiarity led some reviewers to believe that the DQLCTQ should not be considered as a distinct instrument, worthy to be separately reviewed (Garratt *et al.* 2002b).

Nevertheless, this very nature of the instrument has its own advantages and disadvantages. By including entire parts of the most widely generic and disease-specific instruments, gives the physician the opportunity to assess simultaneously health status, treatment satisfaction and the diabetes-related quality of life. However, by including the DQOL in the questionnaire the new instrument does not improve any of its properties, but inherits all the handicaps that the old instruments carries.

According to the authors the process of questionnaire development and validation followed the Streiner-Norman and the McDowell- Newell model. This seems to be true as far as the validation process is concerned. However, the item generation and scale generation process is not in agreement with the proposed by the above writers methods. Contrary to what the authors of the questionnaire imply, Streiner and Norman (2008) clearly state that items should be generated from five different sources: patients, theory, research, clinical observation, and expert opinion. Compiling tests by collecting items or whole domains from previous inventories is by no means the suggested method. Streiner and Norman strongly express their opposition to this phenomenon by quoting two rather sarcastic comments by Goldberg and Angleitner concerning items that move from one inventory to another (*ibid*).

The method followed by Shen's team was rather a trial-and-error process than the methods proposed by the above authors and supported by FA or PCA. Their method seems to be more similar to what Nunnally and Bernstein years earlier described as "shotgun empiricism". This is the process of gathering large quantities of data and then using statistical tools to get something meaningful, or studying variables without a theoretical basis. The two writers express their opposition to such methods by concluding that:

"Progress in theory must be guided by theories rather than by random efforts to relate things to one another".

These words by Nunnally and Bernstein could serve as a final comment for the DQLCTQ.

8 Diabetes-Specific Quality-of Life Scale

Background

The Diabetes-Specific Quality-of Life Scale (DSQOLS) was developed in Germany by U. Bott and his associates by mid of the 1990s. In English it was first published in 1998 (Bott *et al.* 1998). It is a 64-item scale aiming to assess diabetes-specific quality of life and preference-weighted treatment satisfaction.

Conceptual and Measurement model

The DSQOLS was designed to assess four components of quality of life, namely physical, emotional, social burdens, as well as daily functioning of people with type 1 diabetes (*ibid*).

Item generation

Its development was based on two already existing measures, developed in Germany, and structured group discussions with patients. The selected items were reviewed for item selection and word improvement by two physicians, a diabetes educator, a diet specialist and two pedagogues. The emerged scale consisted of 64 items covering seven domains. Two of them with 20 items concern treatment (treatment goals with 10 items, treatment satisfaction with 10 items), and five concerning diabetes-distress with 44 items (physical complaints 10 items, emotional burdens and worries 8 items, social problems 9 items, daily functions 11 items, and diet restrictions 6 items).

Item reduction – scale generation

Principal Component Analysis was performed for the 44 items concerning diabetes distress in order to explore the structure of the DSQOLS. 6 factors emerged explaining 50.1% of the total variance. Four items that showed unsatisfactory results on factor loading and one in item-scale correlation were removed, leaving a scale with 39 items. The 6 factors are: Social relations with 11 items, leisure time flexibility with 6 items, physical complaints with 8 items, worries about future with

5 items, diet restrictions with 5 items, and daily hassles with 4 items. Last, the 6 factor structure of the measure that had been emerged was confirmed by Confirmatory Factor Analysis.

Scoring method

Each of the 39-item quality of life scale is rated on a six-point Likert scale, with higher scores indicating better quality of life. Preference-weighted treatment satisfaction is calculated by rating patients' treatment goals on a six-point scale, multiplied by the corresponding degree of satisfaction with the achievement of these goals.

Sample

657 patients all with type 1 diabetes agreed to respond answering the DSQOLS questionnaire; 58% of them were male, with a mean age of 36 years, and a mean duration of diabetes of 18 years. The patients were selected from lists of primary care physicians randomly selected from the district of Northrhine – Germany.

Reliability

Cronbach's α was calculated for each subscale of the DSQOLS. The results were to a great extend satisfactory ranging between 0.70 (daily hassles) and 0.88 (social relations). Cronbach's α for the 10 items of the treatment satisfaction scale was 0.77.

Validity and Responsiveness

Content – face validity

The participation of patients, health professionals, and pedagogues in the item development process and the review of the emerging instrument gives evidence about content and face validity.

Construct – convergent validity

The measure was validated for type 1 diabetes only. Convergent validity was assessed against a generic measure, the 6-item Positive Well-being Scale. All six subscales as well as the treatment satisfaction subscale were significantly correlated with the

Well-being scale. Social relations, physical complaints, and leisure time flexibility showed the highest with $r = 0.53$, 0.52 and 0.52 respectively. They were statistically weak correlations between physical complaints, treatment satisfaction and worries about future and glycaemic control with r ranging from -0.17 to -0.22 while all the other subscales' correlation ranged from 0.00 to 0.10 .

Diabetes duration and age showed high correlations with physical complaints and leisure time flexibility, which implies that younger patients and shorter duration of diabetes enjoy a better quality of life. The fact that age and duration of diabetes were highly correlated only to physical components provides, according to the authors further evidence for the construct validity of the scale.

Discriminant validity

The type of insulin intake was significantly related to worries about the future, leisure time flexibility and diet restrictions with insulin-pump users scoring higher scores than patients injecting insulin. Also, patients with a flexible adaptation of insulin dosage (i.e. insulin intake according to food consumption), achieved better scores in social relations, leisure time flexibility, worries, and diet restrictions.

Diabetic complications were highly related to restrictions on quality of life. The degree of retinopathy (i.e. loss of vision), was found to have a linear relationship with low quality of life scores. Thus, social relations, leisure time flexibility, physical complaints, and worries about the future were strongly affected by visual impairment. Patients with diabetes-related nephropathy had also significantly lower scores in leisure time flexibility, physical complaints, worries about the future, as well as positive well-being. Treatment satisfaction subscales were not affected as much as the quality of life ones.

Last, patients with higher social status achieved higher scores in the worries about the future and physical complaints subscales. Also, patients living with a partner showed higher scores in the treatment satisfaction scale.

The results on the discriminant validity of the DSQOLS combined with relevant results reported for the generic Positive Well-being Scale support, according to the authors, the superiority of disease-specific measures relatively to the generic ones. This view, although it is probably correct, does not seem to be absolutely justifiable in this case, taking into consideration that the comparison was between the DSQOLS and a 6-item generic measure, which by no means could be considered as a gold-standard criterion. Nevertheless, the DSQOLS has proved sufficient discriminant validity.

Responsiveness

The responsiveness of the DSQOLS has not been assessed.

Subsequent studies

In 2003 Bott *et al.* published the results concerning a clinical trial for the treatment of diabetes patients with an insulin analogue. In this trial the DSQOLS was used and assessed for its properties. Cronbach's α was calculated for all subscales achieving very good results. The 6 quality of life scales as well as the preference-weighted treatment satisfaction scale showed results ranging from 0.83 to 0.89. The instrument was used to assess the differences between the patients receiving different treatments. The changes in scores from baseline to 6 months show significant improvements in most quality of life domains for both treatment groups. The results were even better for the treatment satisfaction domains of the DSQOLS. The authors concluded that the questionnaire comprehensively covered the crucial diabetes-specific quality of life domains.

Burden and Acceptability

Questionnaire's completion time, according to the authors, is 10-20 min. 657 patients accepted to respond, out of the 684 that were initially asked (96%). 6.5% of them declined or failed to complete the questionnaire.

Alternative forms

In the Bott *et al.* study (*ibid.*) a version of DSQOLS was used containing another five dimensions. These dimensions were: fear of hypoglycaemia, blood glucose fluctuations, burdens of hypoglycaemic events, fear of genetically engineered insulin, and self-efficacy.

Cultural and Language Adaptations

The instrument was developed in Germany and the English version is an adaptation that has not been tested for its properties.

Comments

The Diabetes Specific Quality of Life Scale was developed, validated, and assessed for its psychometric properties in a sample of people with type 1 diabetes. It appears to have high internal consistency, and good construct, convergent and discriminant validity. Thus, the authors are justified in supporting that this tool to be a reliable and valid measure of quality of life related to diabetes. They state that it is a tool that reaches beyond traditional treatment satisfaction scales and that it achieves sufficient sensitivity to distinguish between different treatment and dietary regimen. Moreover, the DSQOLS is a measure capable to assess treatment satisfaction together with the QoL. It can be used to determine patients' QOL according to treatment and diet regimens and to detect social inequalities. This could be represent a considerable advantage, as the assessment of individual treatment goals may be helpful in preparing individual treatment strategies.

Nevertheless, the DSQOLS has certain disadvantages that not only prohibit its use for a study like this, but they also reduce its value as a quality of life measure. First, it concerns type 1 diabetes patients only, practically narrowing its use to relevant clinical trials. Second, it is a relatively lengthy instrument with 39 items addressing quality of life. Last and probably most important for the value of the instrument, is that it was developed, validated, and used only in German. It was translated into

English, with the assumption probably that the instrument keeps its properties in the new version, as no validation publication or use of this translation was found in literature. The decision to include the DSQOLS in this review was only marginal as it well accepted by writers that the properties of an instrument are not ‘built-in’ characteristics (Nunnally and Bernstein, 1994; Streiner and Norman, 2008), and when major changes take place, such as a translation, they have to be tested under their new form. Bott *et al.* seem to ignore Bradley’s suggestion that “*the psychometric properties cannot be assumed to travel well*” (Bradley, 1996).

9 Diabetes - 39

Background

The development of Diabetes 39 (D-39) started in the mid 90’s in N. Carolina- USA and first appeared in literature in 1997. It was developed by GJ Boyer and JA Earp.

Conceptual and Measurement model

The D-39 is an instrument designed to assess diabetes quality of life. To do this D-39 tries to shed light on issues of importance to patients with diabetes and to determine their unmet needs (Boyer and Earp, 1997). The authors clarify from the beginning that throughout the instrument development no attempt was made to define quality of life for the respondent. On the contrary, the developers asked the respondents to select items that best express their own perception of quality of life, by asking them to indicate the impact of each item on it.

Item generation

To create an initial set of 93 quality of life items the authors reviewed the literature on diabetes and quality of life. This was followed by a series of unstructured interviews with diabetes physicians, educators, pharmacists and patients. The 93 items were grouped into 10 categories: Medication, control, anxiety-worry, energy-mobility, sleep, food restrictions, self-acceptance, social-peer burden, co-morbidity

and sexual functioning. The 93 item QoL questionnaire was followed by another 26 item questionnaire, covering demographic, general health and diabetes specific terms. The set of questionnaires was sent to 1000 patients of a diabetes care centre in Cary-NC, 516 of which returned usable anonymous questionnaires.

Item reduction - factor generation

A series of factor analysis with orthogonal rotation was performed, which ended-up in a pilot instrument consisting of 42-item questionnaire in six domains: Energy-mobility (14 items), diabetes control (12 items), anxiety-worry (6 items), social-peer burden (5 items), sexual functioning (3 items) and diabetes medication (2 items). In the next phase of development (Iowa and N. Carolina) the pilot instrument was subjected to confirmatory factor analysis and assessed for reliability and validity. Factor analysis revealed five factors with eigen values >1, which together accounted for about 90.4% of the total variance. Item-scale correlation ranged from 0.45 to 0.83. By reviewing the results, the final version of the instrument emerged, with 39 items in five domains. These domains are: Energy-mobility (15 items), diabetes control (12 items) anxiety-worry (4 items) social-peer burden (5 items) and sexual functioning (3 items).

Samples

The sample used for the first phase of the instruments development of 516 respondents (the Cary sample). 240 of them were males (45.5%), mean age of the total sample was 52.4 years and the mean duration of diabetes was 13.2 years. 159 (32.5%) patients had IDDM and 330 (67.5%) had NIDDM. 125 (27%) of the type II patients were on tablet/diet treatment. 64 patients (11.8) were of Hispanic or Mexican origin the rest of the sample were Caucasians (*ibid*).

The sample of the Iowa study was 165 patients, recruited from a general practice site. 74 (45%) of them were males, the mean age of the sample was 61.6. years and the mean duration of diabetes was 11.5 years. 31 (19%) patients had IDDM and 128 (81%) had NIDDM. 73 (44%) of the type II patients were on tablet/diet treatment. All patients were Caucasians.

The N. Carolina sample consisted of 262 outpatients from a hospital diabetes clinic. 93 of them were male (36%), mean age of the sample was 55.3 years and the mean duration of diabetes was 10.1 years. 25 (9.5%) patients had IDDM and 218 (90%) had NIDDM. 91(35%) of the type II patients were on tablet/diet treatment. 142 patients (53.4) were Afro-Americans, 109 (41.8%) of the sample were of Caucasian origin and the rest were of Hispanic, Asian, or American-Indian origin.

The type I and type II diabetes classification of the patients in the samples is crude and scientifically marginal, as they used the age of 30 years as a cut-off point and those over 30 were classified as type II patients, while the under 30 ones as type I diabetes patients.

Scoring method

The instrument uses a modified Visual Analogue Scale (VAS). The scale ranges from 1(not affected at all) to 7 (extremely affected). Thus a high score indicates bad QoL. The actual measurement of each response requires a transparent ruler, which spots the location of the response, measuring it to the nearest quarter of a centimetre. The scores derived from the items are linearly transformed to 0-100 scales, with the maximum 100 indicating the highest possible negative impact of the disease on quality of life.

Reliability

Internal consistency of the six scales pilot instrument (Cary study) as measured by Cronbach's α , ranged from 0.81 to 0.92. Cronbach's α for the final five scales 39-item questionnaire in the Iowa study ranged between 0.82 and 0.93 and for the Carolina study from 0.81 and 0.93.

A recalculation of α for patients over 75 years of age and for patients with less than high school education produced values well above the minimum acceptable level of 0.70, supporting the internal validity of the instrument.

Validity and Responsiveness

The validity of the pilot questionnaire was assessed by asking the respondents to rate their overall quality of life. The responses to this global rating were correlated with the scores of the six scales of the D-39. There were statistically significant differences among patients with various degrees of diabetes severity in four out of the six domains. IDDM patients scored higher than those with NIDDM. Treatment and duration of diabetes did not cause any differences in scale scores. Patients with no complications had low mean scores on five scales. Those with many co morbid conditions had the highest scores i.e. poor quality of life. Patients who reported depression as a co morbid condition scored significantly higher on all scales compared with those without depression.

Women scored higher than men on the energy-mobility, control and anxiety- worry scales, while men proved to have more troubles on sexual functioning than women. Single people felt a greater impact on energy-mobility and anxiety-worry scales, but less impact on sexual functioning than married ones. These differences, according to the authors, were not always significant, but they were in the anticipated directions. Nevertheless, neither scores assessing the magnitude of the differences were ever published, nor initial hypotheses had been formed to support their argument.

The five scale 30-item instrument was validated in the Iowa and Carolina studies with the use of the SF-36. Due to the reverse scoring method of the two instruments, negative correlation values, indicating positive relationship, between the two measures were predicted. As predicted, strong negative correlations were observed between energy-mobility scale of the D-39 and physical functioning of the SF-36 ($r = -0.71$), anxiety-worry of the D-39 and mental health of SF-36 ($r = -0.64$) and social burden of the D-39 and social functioning of the SF-36 ($r = -0.48$).

Similarly to the Cary study, correlations between the five scales of the D-39 and the global quality of life item were strong. High overall quality of life was reported by

those with low scores on the D-39 scales, with the Iowa sample scoring lower than the Carolina one. Also, similar findings with the Cary study were found with the severity of diabetes and IDDM and NIDDM patients, although for the Carolina sample the scores for control and anxiety-worry scales were not significantly different between the two groups. In the Iowa sample all scales, except the anxiety-worry one showed significant difference among the diabetes-type groups.

Patients with severe co morbidity scored high on the energy-mobility scale. Men reported a worse situation than women only on the sexual functioning scale. Patients over 75 years of age scored higher than younger ones on energy-mobility. Younger patients scored higher on control, anxiety-worry, and social-peer burden. Patients reporting that diabetes was an obstacle to their employment had consistently high scores compared with those reporting no employment disability.

Responsiveness was not assessed.

Burden and Acceptability

Out of 1000 questionnaires sent during the first phase of the development only 542 were returned. The resulting response rate of 53.2% seems to be low and considering that only 516 of them were characterised as “usable” the rate drops to 51.6%. However, this was the “pilot” questionnaire and no conclusion could be drawn from this. The 42-item instrument in the Iowa study had a better performance. Out of the 236 mailed questionnaires 170 returned, giving a satisfactory response rate of 73.3%. Acceptability in the Carolina study was even lower than the initial one. Out of 644 questionnaires sent to patients only 290 returned, yielding a response rate of 45.8%.

By comparing the responses, it is obvious that no safe conclusion could be drawn about the acceptability of the questionnaire. The fact that the 92-item pilot instrument was more acceptable than the 42-item version does not seem reasonable. Also the two studies in Iowa and Carolina, with the same instrument, had a difference in response rates of 27.5%, which again lacks any reasoning. The authors do not seem

to have an answer to this. They only make a general comment, that by looking at background data there not any reasons to believe that non-respondents were in any way different from respondents. This is another reason to conclude that there should be a problem in the administration of the instrument, especially in the Carolina project.

The VAS used is considered to be an easy for the respondent scoring method. A VAS is easily administered by old people as well as by people of low literacy. However, this method could create problems to people with visual impairment. Also, the measurement of the scale with a transparent ruler and quarters of centimetres with rounding to the highest quarter in case a response falls in-between two quarters seems to be a difficult task for the test administrator.

It was difficult during this review to understand the scoring of the instrument. After communicating with the authors, Dr Greg Boyer sent the scoring instructions as well as the scoring software. Only a simple glance at the process justifies the concluding remark, made by the authors in the original paper, suggesting that this method has to be reconsidered, as its precision is unnecessary for the overall scale score.

Alternative forms

None.

Cultural and Language Adaptations

The Diabetes-39 has been translated into several languages. Soon after the publication of the original, the instrument was translated and validated into Danish, Finnish, Norwegian and Swedish (Lloyd *et al.* 1997).

The translated versions showed good internal consistency with Cronbach's α well above 0.70 in all countries. Correlations between SF-36 and D-39 scales were in most cases above 0.40, indicating satisfactory construct validity.

There are translation in French, German and Italian but no validation studies were found. The D-39 has also been adapted to UK English. The D-39 was translated and validated into Spanish for Mexico, but the study is published in Spanish, with abstract only in English (Lopez-Carmona and Rodriguez-Moctezuma, (2006). The instrument was very recently translated and validated into Chinese-Taiwan. Its validity was tested against a generic measure, the SF-36 (Huang 2008). Cronbach's α for all subscales was high, ranging between 0.82 and 0.93. Construct validity was assessed using factor analysis. Known-groups validity was estimated by using various laboratory indicators. This validation process showed that the D-39 has satisfactory levels of validity, although compared with SF-36 it was not proved in all respects superior in assessing QoL.

Comments

The Diabetes-39 is an instrument assessing the QoL of type 1 and 2 diabetes patients by examining the restrictions that diabetes poses in 5 dimensions of life (energy and mobility, diabetes control, anxiety and worry, social burden, and sexual function).

The D-39 seems to be a reliable a valid instrument. However, in the item generation phase of the development though, the authors give a vague reference to patient participation, without explaining their contribution or give details about the number or characteristics of the participants. For item reduction and scale generation the authors used factor analysis and produced an instrument, which in its final version showed remarkable internal consistency with α coefficients well above the limit of 0.70. Test-retest reliability has not been reported neither in the original study nor in the studies followed for translation and adaptation of the D-39 in N. Europe, which took place with the participation of the original senior author.

The D-39 has been assessed for validity by the use of SF-36 and a self-reported global item. Strong correlations of its five scales have been found with the global QoL item, as well as with most of the nine scales, indicating good validity of the instrument. By using demographic variable it was proved that the D-39 can distinguish differences between groups of patients. Nevertheless it should be noted

here that these differences are not quite clear, between the two samples of the second phase. This could be explained by differences in either the administration of the instrument or its acceptability that seem to be major disadvantages for the instrument. The scoring method could also have played a role for these disparities.

10. Problem Areas in Diabetes

Background

The Problem Areas in Diabetes (PAID) scale was developed and tested by W. Polonsky and his associates in the Joslin Diabetes Centre in Boston USA as a tool to measure psychological adjustment to diabetes. It was first published in 1995 (Polonsky *et al.* 1995). Soon afterwards, in 1997, another study was published, concerning the validation of the instrument (Welch *et al.* 1997). The validation process continued with another two studies one in 2000 (Snoec *et al.* 2000) and the other in 2003 (Welch *et al.* 2003). In all studies W. Polonsky, the main author of the PAID scale, was a member of the evaluating teams.

Conceptual and Measurement model

The Problem Areas in Diabetes is a scale aiming to tap the breadth of diabetes-related emotional distress, by trying to trace patient's perspectives on current emotional burden of diabetes. The questionnaire, according to its authors, is designed as a screening measure for clinical research, as well as to help clinicians to identify patients with high level of diabetes distress and formulate interventions on specific problem areas of diabetes.

The PAID Scale is a 20 items single factor instrument. Each item covers a unique area of diabetes-related emotional problems, as they are frequently reported by type 1 and type 2 diabetes patients. These problems, related to living of diabetes and its treatment, include areas such as interpersonal distress, anger, guilt worry, fear, or depressed mood for patients.

Item generation

Items started developing by 10 diabetes experts (physicians, dieticians and nurses) and diabetes patient interviews carried out by the W. Polonsky, the test's main author. The created items were pilot-tested with 25 insulin-requiring patients. Some items were eliminated and some new ones were added resulting to a 20-item test. No details about any theory, literature review or previous experience are given by the authors.

Item reduction - Factor Generation

In the initial publication, by Polonsky *et al.* (1995), there is no reference about empirical assessment of the instrument's dimensionality. Two years later, in another study (Welch *et al.* 1997) Principal Component Analysis was performed, which showed item loadings of >0.30 for all 20 items on one principal component, accounting for 52.4% of the total variance. This pattern of loadings proved the existence of one factor and supported the summation of the 20 items into a total score.

The one factor conclusion of the Welch study was confirmed by another study in Amsterdam-the Netherlands, by Snoek *et al.* (2000). In this study the Principal Component Analysis was followed by Exploratory Factor Analyses. A forced 4 factor EFA with oblimin rotation found four sub-dimensions: Diabetes-related emotional problems (12 items), treatment problems (3 items), food-related problems (3 items) and social support problems (2 items). In the Dutch study, by reanalysing data from the Welch-USA sample, was proved that the 4-factor model was statistically superior to the 1-factor model, although this superiority was only marginal.

Scoring method

Initially, patient's responses were rated on a 6-point Likert scale, with 1 indicating a "not a problem" condition and 6 a "serious problem". The total score was a summary score, computed by adding the total item responses and the raw item scores

producing a total response ranging between 24 and 143. Later, the response scale changed to a 5-point scaling. 1 indicates the “not a problem” condition and 4 the “serious problem”. The result is converted to 0-100 scale by multiplying the summated item score by 1.25.

Samples

The sample for the original study in Joslin Diabetes Centre was 451 female patients with a mean age of 36.3 years. 82.4% had diabetes type 1, 17.6% of them had diabetes type 2. Their mean duration of diabetes was 15.9 years and 39.3% of them had completed college. 256 patients responded for the second study in the USA. This time the sample was mixed with 47.7% male and 52.3% female patients. Their mean age for the total sample was 52.3 years and their mean duration of diabetes 15.1 years. The onset of diabetes was used as the classification criterion for type 1 and type 2 diabetes. Patients, who had diabetes under the age of 40, were classified as type 1 and the remainder were classified as type 2. Thus, 135 (52.6%) patients were classified as IDDM and 121 (47.3%) as NIDDM, 85 (33.2%) of them on insulin treatment.

In the Dutch study 1,472 patients participated, 750 (51%) men and 722 (49%) women. The mean age of the sample was 51 years and the mean duration of diabetes 16 years. 739 (50.2%) patients were classified as having diabetes type 1 and 701 (47.6%) as having type 2 (32 patients were not classified due to missing data.). 199 type 2 patients (13.5%) were treated with tablets and/or diet. This study used also data from the second USA sample of the 256 patients.

Reliability

Reliability assessment in the original study found a Cronbach's α 0.95, indicating a high level of internal consistency. Item-total correlations were found in the range 0.32 to 0.84 with a mean of 0.68 (Polonsky *et al.* 1995). The second study in the USA showed the same high level of α .

Findings for internal consistency in the Dutch study were similar to the USA ones giving Cronbach's α s of 0.93 and 0.95 for the total PAID and the two randomly divided subgroups of the sample. Examining the internal consistency of the 4 sub-dimensions of the PAID, found in the Welch study, Cronbach's α s ranged between 0.69 (social support) and 0.93 (emotions).

Test-retest reliability was assessed with completion of the questionnaire by 202 people with a mean period of 66 days after the first administration. Pearson's correlation between the two assessments was 0.83 for the total PAID and for the sub-dimensions ranging between 0.74 (food) and 0.80 (emotions).

Validity and Responsiveness

Both types of criterion validity i.e. concurrent and predictive, of the PAID scale were tested in the initial study (Polonsky et al. 1995).

Concurrent validity was assessed by examining the correlations between PAID and psychosocial factors, regimen adherence, long-term glycaemic control and demographic factors. The Brief Symptom Inventory (BSI), the Bulimia Test-Revised (BULIT-R), the worry sub-scale of the Hypoglycaemia Fear Survey (HFS-W), and HbA_{1c} were used as external measures. From the BSI, a nine symptom dimensions and three global distress indices, only the Global Severity Index (GSI) was used, which measures current or past level of symptomatology.

The PAID was highly associated with general emotional distress of the GSI (0.63), with fear of hypoglycaemia of the HFS-W (0.57), and disordered eating of BULIT-R (0.61). Correlations between the PAID and adherence to self-care behaviours of the SCI were negative at a moderate to statistically insignificant level (food 0.49, exercise 0.09). Glycaemic control and PAID were positively correlated at a moderate level (0.30). Age and duration of diabetes had a statistically insignificant level of negative correlation with PAID.

To determine the **predictive** validity of the PAID, approximately two years after the test's administration, medical records of 221 patients from the initial sample was examined for the most recent HbA_{1c} results. The examination was performed at least one year from baseline (average 533 days). Statistical analysis proved that the PAID has insignificant clinical importance in the determination of future glycaemic control at about one year's time. The authors argue that its predictive validity could be important only for patients who have a clinically significant change in glycaemic control.

Concurrent validity was again evaluated in the Welch study (1997) by examining the correlations between the PAID and other measures. To this end, correlations were calculated separately for four sub-groups divided according to the treatment (type 1 diabetes and type 2 with insulin, tablets or diet treatment) between the PAID and various other measures. These were the attitude scale of the Health Belief Model (HBM), the Diabetes Social Support scale (DSS), and four diabetes-specific coping subscales that emerged from a psychological adjustment to diabetes measure, the ATT 39 and the Diabetes Coping Measure (DCM). The results showed that the PAID was correlating highly, as expected, with the four coping subscales, the HBM scale, and moderately to strong with the DSS for most of the four sub-groups.

Discriminant validity was assessed by examining the differences between IDDM and NIDDM treatment groups by using multiple regression analyses. The contributions of the four type/treatment sub-groups to the total PAID scores were examined, adjusting for sex, duration of diabetes and age of diabetes onset. Type 1 diabetes patients scored significantly higher than type 2 ones, irrespectively of treatment, on the total PAID score. No significant differences were found between insulin and tablet treated type 2 patients, contrary to the initial prediction. Duration of diabetes and gender were not significantly correlated to the PAID. Also, the correlations found between the PAID and HbA_{1c} were not statistically significant.

The Dutch study was a cross-sectional one. It examined the PAID for its convergent and discriminative validity and compared the results with the USA studies.

Convergent validity was assessed by examining the correlations of the PAID Scale with other measures and medical variables. There was a low positive association between the PAID and HbA_{1c} (0.11), as well as the Self-Monitoring of Blood Glucose (0.13). The authors claim that this low correlation was expected.

Moderately high correlations (0.30 – 0.50) were expected between the PAID scale and the other impact measures. All associations found confirmed their hypotheses. Perceived burden of diabetes correlated strongly with total PAID (0.60). A negative moderate correlation was found with overall satisfaction with life (-0.46). Perceived health status had an also negative correlation of -0.35 with the total PAID. Women showed higher total PAID scores than men.

Discriminative validity was assessed by comparing the total PAID scores with various subgroups. People with a history of psychological/psychiatric treatment or with one or more hypoglycaemic crises in the previous six months had significantly higher scores on the total PAID. Also people with one or more diabetes ketoacidosis (DKA) episodes had higher score on total PAID.

Responsiveness

The fourth subsequent study examined the responsiveness of the PAID (*Welch et al.* 2003). Welch and his team obtained longitudinal data from seven diabetes treatment interventions that took place between 1999 and 2001. The interventions were of medical, educational and psychological nature. The clinical settings were of all three care levels; primary, secondary and university's tertiary institutions. All sociodemographic and clinical data together with the PAID scores were statistically analysed and responsiveness was calculated using a dependent t-test and by calculating the effect size using Cohen's effect size. The results of this study showed that the PAID has a low to moderate responsiveness, with Cohen's effect size ranging between 0.32 and 0.64, and half of the results being in the >0.50 range (moderate). The dependent t-test, which was probably used due to the small sample sizes of the studies, showed values ranging from 8.5 to 2.1.

Burden and Acceptability

Completion time is reported to be 3-5 minutes. In the first test out of 531 patients asked to participate 451 responded, giving an acceptance rate of 84, 9%. This rate fell to 70% in the second USA study. In the Dutch study 3,000 questionnaires were mailed to members of the Dutch Diabetes Association and 1472 of them were returned giving a rate of 49%. When test-retest reliability was assessed in this study, the response rate was 81%.

Alternative forms

In a paper published by Polonsky in 2000 (*op.cit*), it was announced that the PAID had been revised and the PAID-2 was already developed and that the relevant publication was in preparation. The revised instrument, longer than the original, consisted of 28 items, with four diabetes-specific dimensions: overall emotional distress, interpersonal distress, regimen-related distress, and physical-related distress. Although the PAID-2 questionnaire can be retrieved from the internet (PAID-2), no trace of further discussion about the revised instrument could be found.

Cultural and Language Adaptations

The PAID has been translated into several languages. These are: Chinese, Finnish, Danish, Japanese, Portuguese + for Brazil, German, Spanish, Dutch, Swedish and Icelandic. Three years after Polonsky's announcement about the revision of the PAID the instrument was translated and validated into Spanish for Mexicans. (Lerman-Garber *et al.* 2003). The psychometric properties of the translated instrument could not be considered reliable as the sample consisted of 20 patients only.

During the writing of this review two new validated translations appeared in literature. One in Icelandic (Sigurdardottir and Benediktsson, 2008) and the other one in Swedish (Amsberg *et al.* 2008).

The Swedish translation followed the established forward-backward translation process. To adapt the PAID to the Swedish health system, in which the diabetes-nurses are an important part of care provision, one item was deleted (coping with complications) and another one was added (satisfaction with diabetes-specialist nurse). In this study, the exploratory factor analysis performed revealed one factor accounting for 46% of the variance. A further Principal Component Analysis was carried out in order to derive independent sub-scales. The PCA, contrary to the Welch study revealed three sub-dimensions: diabetes-related emotional problems (15 items), treatment-related problems (2 items) and support-related problems (3 items). Cronbach's α for the total score was 0.94 and varied between 0.61 (support problems) and 0.94 (emotional problems). Item total correlations ranged from 0.34 to 0.85. Convergent validity was assessed by calculating correlations coefficients between the Swe-PAID and the Swedish version of the Hypoglycaemia Fear Survey (HFS) as well as HbA_{1c}. The total Swe-PAID showed a moderate positive correlation with the total HFS ($r=0.45$) and a low positive correlation ($r=0.25$) with HbA_{1c}.

The Icelandic translation followed the forward-backward translation technique. Factor analysis was performed revealing two factors: Distress in relation to life with diabetes, and distress in relation to management of diabetes. Cronbach's α for these factors were 0.88 and 0.94 respectively. The translators claim that the measure showed good convergent and discriminant validity.

Comments

The whole process of development, revision and adaptation of the PAID seems to be unusual. The author recognised some imperfections of the measure and in 2000 announced a revision of it. Although the revised PAID questionnaire was produced it remained unused and untested. Meanwhile the measure was translated into other languages (e.g. Spanish for Mexicans). Polonsky himself, three years after his

announcement, was member of a team that assessed the responsiveness of the PAID (Welch *et al.* 2003).

In a paper published in 2005 by Polonsky *et al.* the measure was criticised as insufficient and they announced the creation of a new instrument: the Diabetes Distress Scale (DDS). The criticism was mainly focused on three areas: First, the inability of the PAID to cover some critical areas of diabetes. Second, the authors discovered that some items created confusion to respondents over the exact meaning of the question. And third, the PAID-2, with its 28 items, was considered to be a lengthy instrument. Thus, the whole attempt seems to have been abandoned and the DDS is the measure that has been proposed instead. However the PAID, as the two 2008 translations indicate, still attracts the attention of some researchers for reasons that have not been understood yet and should be investigated with personal communication in the near future.

11 The Diabetes Distress Scale (DDS)

Background

The Diabetes Distress Scale is the latest instrument that appeared in the literature of diabetes-specific QoL instruments. It was developed by WH Polonsky and his associates in the USA and it was published in 2005. The reason for its development, according to the authors, was to address some of the limitations that other previously developed instruments have, such as the PAID, the QSD-R, and the ATT-39.

Conceptual and Measurement model

The DDS is a 17 item scale aiming to assess the diabetes-related emotional distress for use in research and clinical practice. It contains items from four domains of diabetes-related distress. 5 of them addressing emotional burden (EB), 5 regimen-

related distress (RD), 4 physician-related distress (PD) and 3 diabetes-related interpersonal distress (ID).

Item generation

A revision of the items of the three previous instruments was performed by patients, diabetes-nurse specialists, dieticians, diabetologists, and diabetes-knowledgeable psychologists. A pool of 50 items was initially derived from four pre-established domains (EB, RD, PD, and ID). These items were tested with patients and a 28 items scale emerged. A brief examination of these items reveals that the instrument proposed is the revised PAID that was announced by Polonski in 2000 but never appeared in literature.

Item reduction – scale generation

Exploratory Factor Analysis was performed for the 28 items scale in four different test-sites. Different results occurred and it was decided to retain four factors, addressing the four pre-established domains and retest the scale with data from all four sites together. From this analysis, and after retaining only the items with a high loading on one factor, a shorter scale emerged containing 17 items. The correlation between the 28-item and the 17-item scale was examined and found to be extremely high ($r = 0.99$), something that supports the reduction of items. Also, the mean correlation between the subscales was very good with total score $r = 0.82$.

Scoring method

Respondents are asked to rate the degree to which each item represented a problem to them in a 6-point Likert scale, ranging from 1 (no problem) to 6 (serious problem).

Samples

Four different samples were used at four different test sites. Two of them were in diabetes clinics in Dan Diego USA, one in Boston and one in Honolulu. The total number of respondents was 683. 52.3% of them were male, with a mean age of 56.3 years and a mean duration of diabetes of 12.8 years. 83.3% had type 2 diabetes,

50.4% of them were insulin users and 88.7% of them had high school education. Acceptability rate was at 72% of the sample.

Reliability

Cronbach's α was estimated to be at the high level of 0.93 for the combined sample of the four test sites. For the four subscales alphas were: 0.88 for EB, ID, and PD, and 0.90 for RD. No other form of reliability has been reported.

Validity and Responsiveness

The validity assessment of the DDS, according to its authors, was relatively limited (Polonsky *et al.* 2005:630). However, it was assessed by calculating Pearson correlation coefficients between the total scale, its four subscales and the CESD (Centre for Epidemiological Studies Depression scale), disease management, and HbA_{1c}. It was found that the DDS total was unrelated to glycaemic control ($r = 0.01$) as well as sex, ethnicity, educational level, or diabetes duration. DDS total scores were positively related with depressive symptomatology as measured by CESD ($r = 0.56$), regimen type with insulin users reporting the highest DDS total scores. It was also positively related to total cholesterol ($r = 0.20$) and to poorer adherence to meal planning recommendations ($r = 0.30$). Age was negatively correlated with the total score, indicating that young patients report greater diabetes-distress than old ones.

Responsiveness was not assessed.

Burden and Acceptability

There is no reference for the time necessary for completion of the DDS. The authors suggest that the time needed for the DDS completion as well as the other two instruments concerning psychological functioning, self-care behaviours and clinical variables is about 15-20 minutes, which seems to be a quite short period of time for so many different items and variables.

Alternative forms

None.

Cultural and Language Adaptations

None.

Comments

The DDS seems to have some certain qualities. It is a relatively short instrument, with clear to the respondent items. It is a diabetes-burden measure addressing four different types of diabetes-distress. However, it has not been assessed properly for its validity and reliability. No study has been designed to assess these psychometric properties, as none of the mentioned four separate studies were designed for it. A lot of further work is needed before it could be considered as a useful instrument. Last, it should be taken into consideration that the DDS addresses the diabetes related distress only and no other domains of quality of life.

Appendix B: The ADDQoL-Gr

ADDQoL

Το ερωτηματολόγιο αυτό ρωτά για την ποιότητα της ζωής σας – με άλλα λόγια πόσο καλή ή κακή νοιώθετε ότι είναι.

Παρακαλώ βάλτε ένα "X" στο κουτάκι, το οποίο υποδηλώνει καλλίτερα την απάντησή σας σε κάθε ερώτηση.

Αυτό που θα θέλαμε να ξέρουμε είναι πώς εσείς νιώθετε για τη ζωή σας τώρα.

I) Σε γενικές γραμμές, η τωρινή ποιότητα ζωής μου είναι:						
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
εξαιρετική	πολύ καλή	καλή	ούτε καλή ούτε κακή	κακή	πολύ κακή	υπερβολικά κακή

Τώρα θα θέλαμε να ξέρουμε το πώς η ποιότητα της ζωής σας επηρεάζεται από το διαβήτη σας, τη διαχείρισή του και τις τυχόν επιπλοκές που μπορεί να έχετε.

II) Εάν <u>δεν</u> είχα διαβήτη, η ποιότητα ζωής μου θα ήταν:				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
πάρα πολύ καλύτερη	πολύ καλύτερη	λίγο καλύτερη	η ίδια	χειρότερη

Παρακαλούμε απαντήστε στις πιο συγκεκριμένες ερωτήσεις που ακολουθούν στις επόμενες σελίδες. Για κάθε πλευρά της ζωής που περιγράφεται, θα βρείτε δύο μέρη:

Για το Μέρος (α): βάλτε ένα "X" σε ένα κουτάκι για να δείξετε πώς ο διαβήτης επηρεάζει αυτήν την πλευρά της ζωής σας.
Για το Μέρος (β): βάλτε ένα "X" σε ένα κουτάκι για να δείξετε πόσο σημαντική είναι αυτή η πλευρά της ζωής σας στην ποιότητα ζωής σας.

1	(α) Εάν <u>δεν</u> είχα διαβήτη, θα απολάμβανα τις δραστηριότητες του ελεύθερου χρόνου μου:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		πάρα πολύ περισσότερο	πολύ περισσότερο	λίγο περισσότερο	το ίδιο	λιγότερο
	(β) Για εμένα, οι δραστηριότητες του ελεύθερου χρόνου μου είναι κάτι το:	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		πολύ σημαντικό	σημαντικό	κάπως σημαντικό	καθόλου σημαντικό	

2	Αυτό τον καιρό εργάζεστε, ψάχνετε για εργασία ή θα θέλατε να εργαστείτε; Ναι <input type="checkbox"/> Όχι <input type="checkbox"/>					
	Εάν <u>ναι</u> συμπληρώστε το (α) και το (β), εάν <u>όχι</u> πηγαίνετε απευθείας στο 3α.					
	(α) Εάν <u>δεν</u> είχα διαβήτη, η εργασιακή μου ζωή θα ήταν:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		πάρα πολύ καλύτερη	πολύ καλύτερη	λίγο καλύτερη	ίδια	χειρότερη
	(β) Για εμένα, το να έχω εργασιακή ζωή είναι:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		πολύ σημαντικό	σημαντικό	κάπως σημαντικό	καθόλου σημαντικό	

3	(α) Εάν <u>δεν</u> είχα διαβήτη, τοπικές μετακινήσεις ή μεγάλα ταξίδια θα ήταν:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		πάρα πολύ ευκολότερα	πολύ ευκολότερα	λίγο ευκολότερα	τα ίδια	πιο δύσκολα
	(β) Για εμένα, τοπικές μετακινήσεις ή μεγάλα ταξίδια είναι κάτι το:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		πολύ σημαντικό	σημαντικό	κάπως σημαντικό	καθόλου σημαντικό	

4	<p>Πάτε ποτέ διακοπές ή θέλετε να πάτε διακοπές; Ναι <input type="checkbox"/> Όχι <input type="checkbox"/></p> <p>Εάν ναι συμπληρώστε το (α) και το (β), εάν όχι πηγαίνετε απευθείας στο 5α.</p>
(α)	<p>Εάν δεν είχα διαβήτη, οι διακοπές μου θα ήταν:</p> <p><input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p> <p>πάρα πολύ πολύ καλύτερες λίγο καλύτερες ίδιες χειρότερες καλύτερες</p>
(β)	<p>Για εμένα, οι διακοπές είναι κάτι το:</p> <p><input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p> <p>πολύ σημαντικό σημαντικό κάπως σημαντικό καθόλου σημαντικό</p>

5 (α)	<p>Εάν δεν είχα διαβήτη, σωματικά θα μπορούσα να κάνω:</p> <p><input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p> <p>πάρα πολύ πολύ λίγο τα ίδια λιγότερα περισσότερα περισσότερα περισσότερα</p>
(β)	<p>Για εμένα, το πόσα μπορώ να κάνω σωματικά είναι:</p> <p><input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p> <p>πολύ σημαντικό σημαντικό κάπως σημαντικό καθόλου σημαντικό</p>

6	<p>Έχετε οικογένεια / συγγενείς; Ναι <input type="checkbox"/> Όχι <input type="checkbox"/></p> <p>Εάν ναι συμπληρώστε το (α) και το (β), εάν όχι πηγαίνετε απευθείας στο 7α.</p>
(α)	<p>Εάν δεν είχα διαβήτη, η οικογενειακή μου ζωή θα ήταν:</p> <p><input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p> <p>πάρα πολύ πολύ καλύτερη λίγο καλύτερη ίδια χειρότερη καλύτερη</p>
(β)	<p>Η οικογενειακή μου ζωή είναι κάτι το:</p> <p><input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p> <p>πολύ σημαντικό σημαντικό κάπως σημαντικό καθόλου σημαντικό</p>

7 (α)	<p>Εάν δεν είχα διαβήτη, οι φιλίες μου και η κοινωνική ζωή μου θα ήταν:</p> <p><input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p> <p>πάρα πολύ πολύ καλύτερες λίγο καλύτερες ίδιες χειρότερες καλύτερες</p>
(β)	<p>Για εμένα, οι φιλίες μου και η κοινωνική ζωή μου είναι κάτι το:</p> <p><input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p> <p>πολύ σημαντικό σημαντικό κάπως σημαντικό καθόλου σημαντικό</p>

8	Έχετε ή θα θέλατε να έχετε μια στενή προσωπική σχέση(π.χ. σύζυγο ή σύντροφο); Ναι <input type="checkbox"/> Όχι <input type="checkbox"/> Εάν <u>ναι</u> συμπληρώστε το (α) και το (β), εάν <u>όχι</u> πηγαίνετε απευθείας στο 9.
(α)	Εάν <u>δεν</u> είχα διαβήτη, η πιο στενή προσωπική μου σχέση θα ήταν: <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> πάρα πολύ πολύ καλύτερη λίγο καλύτερη ίδια χειρότερη καλύτερη
(β)	Για εμένα, το να έχω μια στενή προσωπική σχέση είναι κάτι το: <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> πολύ σημαντικό σημαντικό κάπως σημαντικό καθόλου σημαντικό

9	Έχετε ή θα θέλατε να έχετε σεξουαλική ζωή; Ναι <input type="checkbox"/> Όχι <input type="checkbox"/> Εάν <u>ναι</u> συμπληρώστε το (α) και το (β), εάν <u>όχι</u> πηγαίνετε απευθείας στο 10α.
(α)	Εάν <u>δεν</u> είχα διαβήτη, η σεξουαλική μου ζωή θα ήταν: <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> πάρα πολύ πολύ καλύτερη λίγο καλύτερη ίδια χειρότερη καλύτερη
(β)	Για εμένα, το να έχω σεξουαλική ζωή είναι κάτι το: <input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> πολύ σημαντικό σημαντικό κάπως σημαντικό καθόλου σημαντικό

10 (α)	Εάν <u>δεν</u> είχα διαβήτη, η εμφάνισή μου θα ήταν: <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> πάρα πολύ πολύ καλύτερη λίγο καλύτερη ίδια χειρότερη καλύτερη
(β)	Για εμένα, η εμφάνισή μου είναι κάτι το: <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> πολύ σημαντικό σημαντικό κάπως σημαντικό καθόλου σημαντικό

11 (α)	Εάν <u>δεν</u> είχα διαβήτη, η αυτοπεποίθησή μου θα ήταν: <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> πάρα πολύ πολύ λίγο μεγαλύτερη ίδια μικρότερη μεγαλύτερη μεγαλύτερη
(β)	Για εμένα, η αυτοπεποίθησή μου είναι κάτι το: <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> πολύ σημαντικό σημαντικό κάπως σημαντικό καθόλου σημαντικό

12 (α)	Εάν <u>δεν</u> είχα διαβήτη, τα κίνητρά μου για ζωή θα ήταν:				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	πάρα πολύ καλύτερα	πολύ καλύτερα	λίγο καλύτερα	ίδια	χειρότερα
(β)	Για εμένα, τα κίνητρά μου για ζωή είναι κάτι το:				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	πολύ σημαντικό	σημαντικό	κάπως σημαντικό	καθόλου σημαντικό	

13 (α)	Εάν <u>δεν</u> είχα διαβήτη, ο τρόπος με τον οποίο σε γενικές γραμμές οι άνθρωποι αντιδρούν σε μένα θα ήταν:				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	πάρα πολύ καλύτερος	πολύ καλύτερος	λίγο καλύτερος	ίδιος	χειρότερος
(β)	Ο τρόπος που σε γενικές γραμμές οι άνθρωποι αντιδρούν σε μένα είναι κάτι το:				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	πολύ σημαντικό	σημαντικό	κάπως σημαντικό	καθόλου σημαντικό	

14 (α)	Εάν <u>δεν</u> είχα διαβήτη, τα συναισθήματα μου για το μέλλον (π.χ. ανησυχίες, ελπίδες) θα ήταν:				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	πάρα πολύ καλύτερα	πολύ καλύτερα	λίγο καλύτερα	ίδια	χειρότερα
(β)	Για εμένα, τα συναισθήματα μου για το μέλλον είναι κάτι το:				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	πολύ σημαντικό	σημαντικό	κάπως σημαντικό	καθόλου σημαντικό	

15 (α)	Εάν <u>δεν</u> είχα διαβήτη, η οικονομική μου κατάσταση θα ήταν:				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	πάρα πολύ καλύτερη	πολύ καλύτερη	λίγο καλύτερη	ίδια	χειρότερη
(β)	Για εμένα, η οικονομική μου κατάσταση είναι κάτι το:				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	πολύ σημαντικό	σημαντικό	κάπως σημαντικό	καθόλου σημαντικό	

16 (α)	Εάν <u>δεν</u> είχα διαβήτη, οι συνθήκες διαβίωσης μου θα ήταν:				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	πάρα πολύ καλύτερες	πολύ καλύτερες	λίγο καλύτερες	ίδιες	χειρότερες
(β)	Για εμένα, οι συνθήκες διαβίωσης μου είναι κάτι το:				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	πολύ σημαντικό	σημαντικό	κάπως σημαντικό	καθόλου σημαντικό	

17 (α)	Εάν <u>δεν</u> είχα διαβήτη, η εξάρτησή μου από άλλους παρά τη θέλησή μου θα ήταν:				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	πέρα πολύ μικρότερη	πολύ μικρότερη	λίγο μικρότερη	ίδια	μεγαλύτερη
(β)	Για εμένα, το να μη χρειάζεται να εξαρτώμαι από άλλους είναι κάτι το:				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	πολύ σημαντικό	σημαντικό	κάπως σημαντικό	καθόλου σημαντικό	

18 (α)	Εάν <u>δεν</u> είχα διαβήτη, η ελευθερία μου να τρώω όπως εγώ επιθυμώ θα ήταν:				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	πέρα πολύ μεγαλύτερη	πολύ μεγαλύτερη	λίγο μεγαλύτερη	ίδια	λιγότερη
(β)	Για εμένα, η ελευθερία μου να τρώω όπως εγώ επιθυμώ είναι κάτι το:				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	πολύ σημαντικό	σημαντικό	κάπως σημαντικό	καθόλου σημαντικό	

19 (α)	Εάν <u>δεν</u> είχα διαβήτη, η ελευθερία μου να πίνω όπως εγώ επιθυμώ (π.χ. χυμούς, αλκοόλ, ζαχαρούχα ζεστά και κρύα ποτά) θα ήταν:				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	πέρα πολύ μεγαλύτερη	πολύ μεγαλύτερη	λίγο μεγαλύτερη	ίδια	λιγότερη
(β)	Για εμένα, η ελευθερία μου να πίνω όπως εγώ επιθυμώ είναι κάτι το:				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	πολύ σημαντικό	σημαντικό	κάπως σημαντικό	καθόλου σημαντικό	

Εάν υπάρχουν κάποιοι άλλοι τρόποι, εκτός από τους παραπάνω, με τους οποίους ο διαβήτης, η διαχείρισή του και οι όποιες επιπλοκές του επηρεάζουν την ποιότητα της ζωής σας, παρακαλούμε να τους αναφέρετε παρακάτω:

Σας ευχαριστούμε για τη συμπλήρωση αυτού του ερωτηματολογίου

Appendix C: The GB-ADDQoL

ADDQoL

This questionnaire asks about your quality of life – in other words how good or bad you feel your life to be.

Please put an "X" in the box that best indicates your response for each item.

What we would like to know is how you feel about your life now.

I) In general, my present quality of life is:

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
excellent	very good	good	neither good nor bad	bad	very bad	extremely bad

Now we would like to know how your quality of life is affected by your diabetes, its management and any complications you may have.

II) If I did not have diabetes, my quality of life would be:

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
very much better	much better	a little better	the same	worse

Please respond to the more specific statements on the following pages. For each aspect of life described, you will find two parts:

For Part (a): put an "X" in one box to show how diabetes affects this aspect of your life;
For Part (b): put an "X" in one box to show how important this aspect of your life is to your quality of life.

1 (a)	If I did <u>not</u> have diabetes, I would enjoy my leisure activities:				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	very much more	much more	a little more	the same	less
(b)	My leisure activities are:				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	very important	important	somewhat important	not at all important	

2	Are you currently working, looking for work or would you like to work?				
	Yes <input type="checkbox"/> If yes , complete (a) and (b).				
	No <input type="checkbox"/> If no , go straight to 3a.				
(a)	If I did <u>not</u> have diabetes, my working life would be:				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	very much better	much better	a little better	the same	worse
(b)	For me, having a working life is:				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	very important	important	somewhat important	not at all important	

3 (a)	If I did <u>not</u> have diabetes, local or long distance journeys would be:				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	very much easier	much easier	a little easier	the same	more difficult
(b)	For me, local or long distance journeys are:				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	very important	important	somewhat important	not at all important	

4	Do you ever go on holiday or want to go on holiday?				
	Yes <input type="checkbox"/> If yes , complete (a) and (b).				
	No <input type="checkbox"/> If no , go straight to 5a.				
(a)	If I did <u>not</u> have diabetes, my holidays would be:				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	very much better	much better	a little better	the same	worse
(b)	For me, holidays are:				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	very important	important	somewhat important	not at all important	

5	(a) If I did <u>not</u> have diabetes, physically I could do:				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	very much more	much more	a little more	the same	less
(b)	For me, how much I can do physically is:				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	very important	important	somewhat important	not at all important	

6	Do you have any family / relatives?				
	Yes <input type="checkbox"/> If yes , complete (a) and (b).				
	No <input type="checkbox"/> If no , go straight to 7a.				
(a)	If I did <u>not</u> have diabetes, my family life would be				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	very much better	much better	a little better	the same	worse
(b)	My family life is:				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	very important	important	somewhat important	not at all important	

7	(a) If I did <u>not</u> have diabetes, my friendships and social life would be:				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	very much better	much better	a little better	the same	worse
(b)	My friendships and social life are:				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	very important	important	somewhat important	not at all important	

8	Do you have or would you like to have a close personal relationship (e.g. husband / wife, partner)?				
	Yes <input type="checkbox"/> If yes , complete (a) and (b).				
	No <input type="checkbox"/> If no , go straight to 9.				
(a)	If I did not have diabetes, my closest personal relationship would be:				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	very much better	much better	a little better	the same	worse
(b)	For me, having a close personal relationship is:				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	very important	important	somewhat important	not at all important	

9	Do you have or would you like to have a sex life?				
	Yes <input type="checkbox"/> If yes , complete (a) and (b).				
	No <input type="checkbox"/> If no , go straight to 10a.				
(a)	If I did not have diabetes, my sex life would be:				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	very much better	much better	a little better	the same	worse
(b)	For me, having a sex life is:				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	very important	important	somewhat important	not at all important	

10 (a)	If I did not have diabetes, my physical appearance would be:				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	very much better	much better	a little better	the same	worse
(b)	My physical appearance is:				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	very important	important	somewhat important	not at all important	

11 (a)	If I did not have diabetes, my self-confidence would be:				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	very much better	much better	a little better	the same	worse
(b)	My self-confidence is:				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	very important	important	somewhat important	not at all important	

12 (a)	If I did <u>not</u> have diabetes, my motivation would be:				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	very much better	much better	a little better	the same	worse
(b)	My motivation is:				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	very important	important	somewhat important	not at all important	

13 (a)	If I did <u>not</u> have diabetes, the way people in general react to me would be:				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	very much better	much better	a little better	the same	worse
(b)	The way people in general react to me is:				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	very important	important	somewhat important	not at all important	

14 (a)	If I did <u>not</u> have diabetes, my feelings about the future (e.g. worries, hopes) would be:				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	very much better	much better	a little better	the same	worse
(b)	My feelings about the future are:				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	very important	important	somewhat important	not at all important	

15 (a)	If I did <u>not</u> have diabetes, my financial situation would be:				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	very much better	much better	a little better	the same	worse
(b)	My financial situation is:				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	very important	important	somewhat important	not at all important	

16 (a)	If I did <u>not</u> have diabetes, my living conditions would be:				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	very much better	much better	a little better	the same	worse
(b)	My living conditions are:				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	very important	important	somewhat important	not at all important	

17 (a)	If I did <u>not</u> have diabetes, I would have to depend on others when I do not want to:				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	very much less	much less	a little less	the same	more
(b)	For me, not having to depend on others is:				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	very important	important	somewhat important	not at all important	

18 (a)	If I did <u>not</u> have diabetes, my freedom to eat as I wish would be:				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	very much greater	much greater	a little greater	the same	less
(b)	My freedom to eat as I wish is:				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	very important	important	somewhat important	not at all important	

19 (a)	If I did <u>not</u> have diabetes, my freedom to drink as I wish (e.g. fruit juice, alcohol, sweetened hot and cold drinks) would be:				
	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	very much greater	much greater	a little greater	the same	less
(b)	My freedom to drink as I wish is:				
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	very important	important	somewhat important	not at all important	

If there are any other ways in which diabetes, its management and any complications affect your quality of life, please say what they are below:

Thank you for completing this questionnaire.

Appendix D: Agreement for the translation of the ADDQoL

3rd March 2008

(1) ROYAL HOLLOWAY, UNIVERSITY OF LONDON

(2) PROFESSOR CLARE BRADLEY

(3) PROFESSOR ANN BOWLING and MR THEODORE PISSIMISSIS

AGREEMENT

for the translation and use of the **Audit of Diabetes Dependent Quality of Life Questionnaire (ADDQoL19)** (Standard UK English (rev. 1.3.06)) in a study of 'Quality of Life for People with Diabetes Mellitus in Greece' at UCL Department of Primary Care and Population Sciences, London.

THIS AGREEMENT dated 3rd March 2008 is made **BETWEEN:**

- (1) **ROYAL HOLLOWAY AND BEDFORD NEW COLLEGE** whose administrative offices are at Egham, Surrey TW20 0EX, England ("the College");
- (2) **CLARE BRADLEY** of the College's Department of Psychology ("Prof Bradley"); and
- (3) **ANN BOWLING and THEODORE PISSIMISSIS** of UCL Department of Primary Care and Population Sciences, Royal Free & University College Medical School, Hampstead Campus, Rowland Hill Street, London NW3 2PF ("Prof Ann Bowling and Theodore Pissimissis").

WHEREAS:

- Prof Ann Bowling and Theodore Pissimissis intend to translate questionnaires in which the copyright is owned by Prof Bradley who is employed by the College.
- Prof Ann Bowling and Theodore Pissimissis intend to carry out a study using questionnaires in which the copyright is owned by Prof Bradley who is employed by the College.
- The College and Prof Bradley agree to grant Prof Ann Bowling and Theodore Pissimissis a licence to use questionnaires defined below strictly on a non-commercial basis in the study described in the Protocol attached hereto subject to the terms of this agreement.

NOW THEREFORE THE PARTIES HEREBY AGREE AS FOLLOWS:

1. Definitions

1.1 "Questionnaire" shall mean:

- **Audit of Diabetes Dependent Quality of Life Questionnaire (ADDQoL19)** (Standard UK English (rev. 1.3.06)) and any modifications thereto or any adaptations or translations thereof.

1.2 "Study" shall mean 'Quality of Life for People with Diabetes Mellitus in Greece', as set out in the Protocol attached hereto.

2. Copyright and Licences Thereto

2.1 Ownership of all copyrights in the Questionnaire vests in Prof Bradley, and nothing in this Agreement shall be construed either expressed or implied as conferring any rights of ownership upon Prof Ann Bowling and Theodore Pissimissis in the Questionnaire.

2.2 Prof Bradley hereby grants to Prof Ann Bowling and Theodore Pissimissis a non-exclusive non-transferrable royalty-free licence during the Licence Period to use the Questionnaire only for their own internal non-commercial research purposes to:

- translate the Questionnaire into Greek;
- use the Questionnaire in the Study;
- make copies of the Questionnaire from a master copy submitted to them only where reasonably necessary for the purpose of carrying out the Study;

- supply only the number of copies of the Questionnaire as is strictly necessary for the purpose of carrying out the Study only to persons requiring them for the purposes of the Study, and where copies of the Questionnaire are distributed in this manner Prof Ann Bowling and Theodore Pissimissis undertake to supply the Questionnaire with the following statement in a covering letter:

"Copyright in these questionnaires is owned by Prof Clare Bradley of Royal Holloway University of London, Egham, Surrey TW20 0EX, England. Your use of the questionnaires is strictly limited to the particular study you are undertaking for Prof Ann Bowling and Theodore Pissimissis and you are not authorised to copy the questionnaires without the express written permission of Prof Bradley. These questionnaires are in continual development and it is important to ensure that any new study uses the most up-to-date version. Please contact Prof Bradley if you require further information about the questionnaires and their continued development or if you wish to make further use of the questionnaires outside the scope of the study you are undertaking for Prof Ann Bowling and Theodore Pissimissis."

3. Acknowledgements

- 3.1 Prof Ann Bowling and Theodore Pissimissis hereby undertake to acknowledge the source of the Questionnaire in any communication reporting on its use or any publication generated directly or indirectly through use of the Questionnaire.

4. Translation Process and Reports

- 4.1 Prof Ann Bowling and Theodore Pissimissis undertake to use their best endeavours to generate a translation of an appropriate quality in accordance with the guidelines set out in Appendix A hereto.
- 4.2 Prof Ann Bowling and Theodore Pissimissis shall supply Prof Bradley with a detailed written report of the process used to generate the translation together with the actual translation generated for the Study.
- 4.3 If, for whatever reason, Prof Ann Bowling and Theodore Pissimissis cannot complete the linguistic validation work or it is delayed by a number of months, they undertake to keep Prof Bradley or her team informed of any such delays or change in circumstances.
- 4.4 In the event that Prof Bradley does not hear from Prof Ann Bowling and Theodore Pissimissis over a long period of time, does not receive a reply to a request for a progress report, or there is no immediate prospect of Prof Ann Bowling and Theodore Pissimissis completing the linguistic validation work when another user wishes to complete the linguistic validation work, Prof Bradley reserves the right to make alternative arrangements for the completion of the work after writing to Prof Ann Bowling and Theodore Pissimissis.
- 4.5 If Prof Bradley has to make alternative arrangements as described in §4.4 above, she undertakes to involve Prof Ann Bowling and Theodore Pissimissis where possible and mutually agreed.
- 4.6 Prof Ann Bowling and Theodore Pissimissis undertake to use their best endeavours to assess the quality of the psychometric properties of the translated Questionnaire in accordance with part 1.3 in Appendix A hereto, and to submit a detailed report of these findings to Prof Bradley.
- 4.7 Prof Ann Bowling and Theodore Pissimissis undertake to supply Prof Bradley with an electronic file containing anonymised data from the study to include the variables listed in Appendix A3.
- 4.8 Prof Bradley undertakes to use the dataset referred to in clause 4.7 solely for the purposes of evaluating the properties of different language versions of the Questionnaire.

5. Publication

- 5.1 Prof Ann Bowling and Theodore Pissimissis shall in confidence supply Prof Bradley with a copy of the text of any proposed communication or publication concerning the Questionnaire authored by Prof Ann Bowling and Theodore Pissimissis or research collaborators to whom they send copies of the Questionnaire no later than thirty days prior to any proposed submission for publication or dissemination of the same.

6. **Representations, Liability and Indemnities**

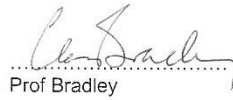
- 6.1 Prof Ann Bowling and Theodore Pissimissis understand that the Questionnaire is experimental in nature. Neither the College nor Prof Bradley make any representations or extend any warranties of any kind, either express or implied, as to the quality or fitness for a particular purpose of the Questionnaire or that the use of the Questionnaire in the Study will not infringe any patent, copyright, trademark, or other rights.
- 6.2 Neither the College nor Prof Bradley shall be liable in any way for the use made of the Questionnaire by Prof Ann Bowling and Theodore Pissimissis pursuant to licences granted to it under this agreement, and Prof Ann Bowling and Theodore Pissimissis hereby agree to defend, indemnify, and hold both the College and Prof Bradley harmless from any loss, claim, damage, or liability howsoever caused arising out of any of Prof Ann Bowling and Theodore Pissimissis' research projects involving the Questionnaire.

Royal Holloway & Bedford New College


Mrs J. Ross

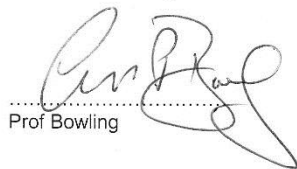
Director of Resources
Position Date 7/3/08

Prof Clare Bradley


Prof Bradley

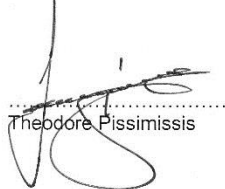
Professor of Health Psychology
Position Date 5.3.08

Prof Ann Bowling


Prof Bowling

Professor of Health Services Research
Position Date 4/4/8

Mr Theodore Pissimissis


Theodore Pissimissis

PhD Student UCL – PCPS Dept
Position Date 16/4/08

PROTOCOL

(Important – the Protocol sets out the scope of the study and must be appended hereto)

\\Trans\\StudyAgmt\\Rev. 6.11.06

The Translation Process

The following process is important in order to ensure a high standard of translation into a new "target" language. The notes taken at the various stages are needed for our records of the translation history, so that we can refer to reasons why certain decisions and choices were made and what clinicians and patients thought. This record is especially important if subsequent psychometric evaluation suggests that improvements to the translation are needed. The translation process is divided into 4 main phases:

- Phase 1 is the main forward and back translation stage (Steps 1-4);
- Phase 2 is the piloting stage (Steps 5-6);
- Phase 3 is the final review stage (Steps 7-8) and, where more than one language is involved, may include international harmonisation (Step 7);
- Phase 4 is the finalisation stage (Steps 9-10).

1. Forward Translation

- 1.1 Two parallel forward translations by native speakers of the target language, fluent in English and resident in the country where the translation is to be used. Ideally one person should be a professional translator and the other a psychologist with experience of psychometric questionnaire design. Familiarity with the disorder to which a questionnaire may relate would be an advantage.
- 1.2 Review of discrepancies and reconciliation of the two forward translations into 1st intermediate forward translation by a third person, who is a native speaker of the target language and fluent in English.
- 1.3 Notes on difficulties found and decisions made (and why) during Step 1.2 for the forward translation report.

2. Back Translation

- 2.1 Two parallel back-translations of the intermediate forward translation, done completely "blind" (i.e. with no help or information about the original English questionnaires) and independently of each other. These should be done by people who are native speakers of English and fluent in the target language.
- 2.2 Review and discussion of discrepancies with back-translators.
- 2.3 Notes on issues raised during Step 2.2 for back-translation report.
- 2.4 Review of back-translation report by the author of the questionnaire, who highlights any concerns.

3. Revisions to Forward Translation

- 3.1 Review by forward translator / translation co-ordinator of any concerns or discrepancies noted during Step 2.
- 3.2 Retranslation where necessary.
- 3.3 Notes on decisions made in Steps 3.1 & 3, together with notes on any items needing particular attention and possible testing of alternatives during clinician review and cognitive debriefing.

4. Repeat of Steps 2 and 3

- 4.1 To be carried out as necessary to produce revised intermediate translation.
- 4.2 Review by the author of the questionnaire of Steps 3 and 4 if required.

5. Review by psychologist and/or clinician

5.1 *By psychologist:*

This step may be particularly useful if the questionnaire is a generic one (e.g. the W-BQ12) and there is no reason for a clinician review; better still if the psychologist has experience of designing questionnaires. Where one of the forward translators is a psychologist (particularly one with experience of questionnaire design) this step would not be necessary.

5.2 *By clinician:*

Where the questionnaire is disorder-specific, review of the revised intermediate translation by a clinician practising in the relevant field (e.g. diabetes, renal disease, ophthalmology) is important. In particular, review of any phrases relating to the nature of the treatment or name of the disorder. It is important to identify the name the clinician gives to the disorder *when talking to patients* (i.e. not necessarily the terms used between health professionals). If one of the forward translators is just such a clinician, this step would not be necessary. If the clinician is simply providing a brief review of the questionnaire and not acting as one of the translators themselves, s/he may not wish to spend time studying the concept translation guidelines, but these should nevertheless be made available to him/her along with the translation, in case s/he has questions about an item. A number of questions can be answered by these documents.

5.3 Notes on suggestions and decisions resulting from both the above steps and notes on any items needing particular attention (or testing of alternatives) during cognitive debriefing need to be included in the report of the translation process.

5.4 Review by the author of the questionnaire.

6. Cognitive Debriefing

6.1 Interviews of approximately five patients with as good a mix as possible, e.g. for the DTSQs & c, ADDQoL, ADKNowI we would aim for the following:

- a) a minimum of 5 people
- b) all with diabetes
- made up of a mixture of the following:
 - c) men and women
 - d) across a good age range
 - e) With Type 1 and 2 diabetes
 - f) the Type 2 patients would ideally include someone on diet alone, someone on tablets and someone on insulin.

6.2 Report by person conducting the interviews, listing:

- a) demographic and known clinical / treatment details of interviewees (these may have a bearing on any notes relating to (b) below);
- b) account of patients' understanding of *all* items, even where the interviewer doesn't think there is a problem. If there are any problematic items, a note of which patient(s) found it problematic and in what way.
- c) selected scores for any of these patients where particularly relevant (e.g. on the DTSQ, if the patients' scores appeared to contradict what they were saying in the interview).

6.3 Review by translation co-ordinator:

- a) Review of any problematic words/phrases/items with forward translators following CD interviews.
- b) Retranslation and back-translation where necessary.
- c) Notes on changes, plus explanations.

6.4 Review by the author of the questionnaire.

7. International Harmonisation

- 7.1 Where several new translations of a questionnaire are being produced, it is valuable to conduct a harmonisation meeting to ensure linguistic equivalence across languages wherever possible. This step is particularly recommended when questionnaires are being prepared for multinational clinical trials.
- 7.2 Notes on changes, plus back-translations and explanations for review by the author of the questionnaire.

8. Review by author and team

When working with Mapi Research Institute on translations, we would normally review the translations after:

- the back-translation step;
- any subsequent retranslation steps;
- clinician / psychologist review;
- cognitive debriefing;
- we would normally be present at any international harmonisation meeting and review the subsequent report.

When sending us translations for review, please let us have:

- 8.1 Latest forward translation in Word and pdf format
- 8.2 Back-translation of latest forward translation
- 8.3 Summary report on comments, changes, problems, queries.
- 8.4 If sending after the piloting phase (i.e. steps 5 and 6), please also include comments/reports from the psychologist, clinician and cognitive debriefing.

9. Production of final version of the questionnaire

9.1 *Formatting*

Please ensure you keep to the original format. We will give you a Word document of the original English that you can use as a template. As you will see from your agreement, you need to keep strictly to this template and not add extras into the header or make any changes to the style. This includes font and font size, unless you are producing e.g. Chinese and you have to produce a translation in a different script. If you need to add e.g. patient number and completion date somewhere, we suggest that you do as others have done and have a separate cover sheet in front of the questionnaire.

9.2 *DTSQc – generic and trial specific versions*

If you are translating the DTSQc, please ensure that you start by producing the generic version of the introduction. If you need to change the wording to be specific to your study, please produce this as a separate version and send both questionnaires to us on completion.

9.3 *Copyright statement*

Please ensure you keep to the copyright statement format (and if the questionnaire has multiple pages, please translate the "Page 1 of 7" as well – see example below). Please add the following statement on a separate line at the bottom of the copyright statement, underneath the Royal Holloway address line:

"Translation conducted by: XXX"

[The name to go here should be the person co-ordinating the translation work]

Examples of copyright statements:

a) For a single page questionnaire:

DTSQs © Prof Clare Bradley 9/93. French for Canada 19.7.02 (from standard UK English rev. 7/94)
Health Psychology Research, Dept of Psychology, Royal Holloway, University of London, Egham, Surrey, TW20 0EX, UK.

b) For a multi-page questionnaire:

ADDQoL © Prof Clare Bradley: 24.2.94. Spanish for Spain 31.7.00 (from standard UK English rev. 3.11.98)
Health Psychology Research, Dept of Psychology, Royal Holloway, University of London, Egham, Surrey, TW20 0EX, UK

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10. Proofreading

An important step sometimes forgotten!

10.1 A new translation needs to be proofread by a native speaker of the target language.

10.2 The questionnaire also needs to be proofread for formatting issues, using the original English format as a template and checked subsequently by a member of Prof Bradley's team who is familiar with the questionnaire.

Reports on Translation and Psychometric Evaluation Processes

As mentioned in the Translation Process Guidelines, a record of the translation process is very important for any future developments that the psychometric analysis may show to be necessary, and also in the event that the translation might need to be adapted for use with other populations. Psychometric analyses form an essential component of the overall validation process.

Translation Process Report

Please send the report on the translation as soon as possible after completion of the work in hard copy and electronic form. The report should include the following (please label everything clearly):

1. Confirmation of the Linguistic Validation Plan or details of any changes made (e.g. change of translator or clinician).
2. Copies of the two forward translations and reconciled forward translation (Step 1.2 as described in "The Translation Process"), together with back-translations of that;
3. Translation report consisting of:
 - 3.1 Forward – back translation report (summarising the notes described in the Translation Process guidelines, Steps 1.3, 2.3 and 3.3 + any additional rounds).
 - 3.2 Clinician and / or psychologist review report(s) (as described in Step 5.3 in "The Translation Process").
 - 3.3 Cognitive debriefing report (as described in Step 6.3 in "The Translation Process").
 - 3.4 Changes following international harmonisation, where included in the process (as described in Step 7.2).
4. The final version of the questionnaire as it is to be used in the study or programme of work. Please ensure that the hard copy of this is a good quality copy, particularly if it is in another script in case we are unable to open the electronic version. If it is in another script that we may not be able to access, we would appreciate receiving it as a .pdf (Acrobat) document if possible. Alternatively, please send a good copy in the regular mail.

Psychometric Evaluation

With any new translation it is necessary to carry out psychometric analyses and in due course we would be very pleased to receive the results of any psychometric analyses conducted. The following are the basic requirements we believe are necessary for those questionnaires that have scales or subscales (e.g. DTSQ, W-BQ, ADDQoL):

1. Confirmatory Factor Analysis (CFA) is recommended on the six treatment satisfaction items in the DTSQ (and for items expected to contribute to scales/ subscales in related –TSQ instruments) (see section 1.1 below) and for all items in the W-BQ (see section 1.2 below), and for all domain-specific items in the ADDQoL (and related measures) (see section 1.3 below). To assess the fit of the hypothesised model to the actual data, at least 24 different fit indices have been proposed. There is no general agreement on a single preferred fit index as yet. It is therefore recommended that a number of measures be presented in describing the 'fit' of a model, e.g. the Comparative Fit Index (FIT), the Bentler-Bonett Normed Fit Index (NFI) and the Tucker Lewis Index (TLI). These three indices are measures of incremental fit and indicate how much better the proposed model fits in comparison to the "baseline" that assumes there are no relationships in the data. Values of these indices range from 0.0 (indicating no fit) to 1.0 (indicating perfect fit) with values >0.90 generally deemed as acceptable. Along with these three indices, the Chi-Square goodness of fit test for the model is usually reported. This test, however, is sensitive to sample size and there is a high probability that a good fitting model is rejected due to small differences between the observed and predicted value. It is mainly due to these limitations of the Chi-Square fit test that other indices have been developed as alternatives.

- 1.1 CFA conducted on the DTSQ measure:
while conducting CFA on the DTSQ only items (or factors) 1,4,5,6,7 and 8 are included. It is recommended that items 3 (perceived frequency of hyperglycaemia) and 3 (perceived frequency of hypoglycaemia) be dropped from this analysis because these items are not expected to load with the other 6 items from the questionnaire.
 - 1.2 CFA conducted on the W-BQ measure will depend on the type of W-BQ questionnaire being used. The most commonly used W-BQ is the 12 item version:
The W-BQ12 includes 3 subscales, namely the Generic Negative Well-being (items 1 to 4), Energy (items 5 to 8) and the Generic Positive Well-being (items 9 to 12). Please note that while defining the model in CFA, each of these 3 subscales will form an 'unobserved variable' connected to the other two unobserved variables using double-headed arrows. Further, the set of items (i.e. observed variables) included in each of these subscales will be contributing to their respective subscales using single-headed arrows.
 - 1.3 CFA conducted on the ADDQoL measure:
Based on earlier psychometric reports involving the ADDQoL (and related measures) it is expected that all domain-specific weighted-impact items (variables) in this measure will load onto one factor or latent variable to indicate the impact of diabetes on quality of life.
2. Reliability analysis with Cronbach's alpha conducted separately for each subscale.

Please let us have hard copy printouts and/or electronic copies of the factor structure and reliability analysis. We use SPSS software and can read documents in Excel and Word, but do not have SAS software.

Please note that for questionnaires containing items that are scored separately and not combined into scales/ subscales (e.g. DCSQ and ADKnowl), there is no necessity for such psychometric evaluation.

Further information to do with scoring, replacing missing scores etc can be found in the manual for the questionnaire.

Appendix E: SF-36v2 Greek

Η υγεία και η ευημερία σας

Το ερωτηματολόγιο αυτό ζητά τις δικές σας απόψεις για την υγεία σας. Οι πληροφορίες σας θα μας βοηθήσουν να εξακριβώσουμε πώς αισθάνεστε και πόσο καλά μπορείτε να ασχοληθείτε με τις συνηθισμένες δραστηριότητές σας. Σας ευχαριστούμε για τη συμπλήρωση αυτού του ερωτηματολογίου!

Παρακαλούμε, σε κάθε ερώτηση που ακολουθεί σημειώστε με ☒ το πλαίσιο που περιγράφει καλύτερα την απάντησή σας.

1. Γενικά, θα λέγατε ότι η υγεία σας είναι:

Άριστη	Πολύ καλή	Καλή	Μέτρια	Κακή
▼	▼	▼	▼	▼
<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

2. Σε σύγκριση με ένα χρόνο πριν, γενικά πώς θα αξιολογούσατε την υγεία σας τώρα;

Πολύ καλύτερη τώρα απ' ότι ένα χρόνο πριν	Κάπως καλύτερη τώρα απ' ότι ένα χρόνο πριν	Περίπου η ίδια όπως ένα χρόνο πριν	Κάπως χειρότερη τώρα απ' ότι ένα χρόνο πριν	Πολύ χειρότερη τώρα απ' ότι ένα χρόνο πριν
▼	▼	▼	▼	▼
<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

SF-36v2™ Health Survey © 1996, 2004 Health Assessment Lab, Medical Outcomes Trust and Quality Metric Incorporated. All rights reserved.
SF-36® is a registered trademark of Medical Outcomes Trust.
(IQOLA SF-36v2 Standard, Greece (Greek))

- 3 Οι παρακάτω προτάσεις περιέχουν δραστηριότητες που μπορεί να κάνετε κατά τη διάρκεια μιας συνηθισμένης ημέρας. Η τωρινή κατάσταση της υγείας σας, σας περιορίζει σε αυτές τις δραστηριότητες; Εάν ναι, πόσο;

Ναί, με περιορίζει Πολύ	Ναί, με περιορίζει Λίγο	Όχι, δεν με περιορίζει Καθόλου
▼	▼	▼

- a. Σε έντονες δραστηριότητες, όπως το τρέξιμο, το σήκωμα βαριών αντικειμένων, ή η συμμετοχή σε επίπονα σπορ..... ☐ 1 ☐ 2 ☐ 3
- b. Σε μέτριας έντασης δραστηριότητες, όπως η μετακίνηση ενός τραπεζιού, το σπρώξιμο μιας ηλεκτρικής σκούπας, το κολύμπι ή όταν παίζετε ρακέτες στην παραλία ☐ 1 ☐ 2 ☐ 3
- c. Όταν σηκώνετε ή μεταφέρετε ψώνια από την αγορά ☐ 1 ☐ 2 ☐ 3
- d. Όταν ανεβαίνετε μερικές σειρές από σκαλοπάτια ☐ 1 ☐ 2 ☐ 3
- e. Όταν ανεβαίνετε μια σειρά από σκαλοπάτια ☐ 1 ☐ 2 ☐ 3
- f. Στο λύγισμα του σώματος, στο γονάτισμα ή στο σκύψιμο ☐ 1 ☐ 2 ☐ 3
- g. Όταν περπατάτε πάνω από ένα χιλιόμετρο..... ☐ 1 ☐ 2 ☐ 3
- h. Όταν περπατάτε μερικές εκατοντάδες μέτρα ☐ 1 ☐ 2 ☐ 3
- i. Όταν περπατάτε εκατό μέτρα ☐ 1 ☐ 2 ☐ 3
- j. Όταν κάνετε μπάνιο ή όταν ντύνεστε ☐ 1 ☐ 2 ☐ 3

4. **Τις τελευταίες 4 εβδομάδες, πόσο συχνά είχατε κάποια από τα παρακάτω προβλήματα στη δουλειά σας ή σε άλλες συνηθισμένες καθημερινές δραστηριότητες ως αποτέλεσμα της κατάστασης της σωματικής σας υγείας;**

	Συνεχώς	Τις περισσότερες φορές	Μερικές φορές	Λίγες φορές	Καθόλου
a. Μειώσατε <u>το χρόνο</u> που συνήθως αφιερώνετε στη δουλειά ή σε άλλες δραστηριότητες.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
b. <u>Καταφέρατε λιγότερα</u> από όσα θα θέλατε.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
c. Περιορίσατε <u>το είδος</u> δουλειάς ή άλλων δραστηριοτήτων σας.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
d. <u>Δυσκολευτήκατε να</u> επιτελέσετε την εργασία ή άλλες δραστηριότητές σας (για παράδειγμα, καταβάλατε μεγαλύτερη προσπάθεια).....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

5. **Τις τελευταίες 4 εβδομάδες, πόσο συχνά είχατε κάποια από τα παρακάτω προβλήματα στη δουλειά σας ή σε άλλες συνηθισμένες καθημερινές δραστηριότητες ως αποτέλεσμα οποιουδήποτε συναισθηματικού προβλήματος (όπως επειδή νοιώσατε μελαγχολία ή άγχος);**

	Συνεχώς	Τις περισσότερες φορές	Μερικές φορές	Λίγες φορές	Καθόλου
a. Μειώσατε <u>το χρόνο</u> που συνήθως αφιερώνετε στη δουλειά ή σε άλλες δραστηριότητες.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
b. <u>Κάνατε λιγότερα</u> από όσα θα θέλατε.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
c. Κάνατε τη δουλειά ή άλλες δραστηριότητες <u>λιγότερο προσεκτικά</u> απ' ό,τι συνήθως.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

6. Τις τελευταίες 4 εβδομάδες, σε ποιο βαθμό επηρέασε η κατάσταση της σωματικής σας υγείας ή συναισθηματικά σας προβλήματα τις συνηθισμένες κοινωνικές σας δραστηριότητες με την οικογένεια, τους φίλους, τους γείτονές σας ή με άλλες κοινωνικές ομάδες;

Καθόλου	Ελάχιστα	Μέτρια	Σε μεγάλο βαθμό	Υπερβολικά
▼	▼	▼	▼	▼
<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

7. Πόσο σωματικό πόνο νιώσατε τις τελευταίες 4 εβδομάδες;

Καθόλου	Πολύ ήπιο	Ηπιο	Μέτριο	Εντονο	Πολύ έντονο
▼	▼	▼	▼	▼	▼
<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6

8. Τις τελευταίες 4 εβδομάδες, πόσο επηρέασε ο πόνος τη συνηθισμένη εργασία σας (τόσο την εργασία έξω από το σπίτι όσο και μέσα σε αυτό);

Καθόλου	Λίγο	Μέτρια	Σε μεγάλο βαθμό	Υπερβολικά
▼	▼	▼	▼	▼
<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

9. Οι παρακάτω ερωτήσεις αναφέρονται στο πώς αισθανόσαστε και στο πώς τα πράγματα πήγαιναν με σας τις τελευταίες 4 εβδομάδες. Για κάθε ερώτηση, παρακαλείστε να δώσετε εκείνη την απάντηση που πλησιάζει περισσότερο σε ό,τι αισθανθήκατε. Τις τελευταίες 4 εβδομάδες, για πόσο χρονικό διάστημα...

	Συνεχώς ▼	Τις περισσότερες φορές ▼	Μερικές φορές ▼	Λίγες φορές ▼	Καθόλου ▼
a. Αισθανόσασταν γεμάτος/γεμάτη ζωντάνια;	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
b. Είχατε πολύ εκνευρισμό;	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
c. Αισθανόσασταν τόσο πολύ πεσμένος/πεσμένη/ψυχολογικά, που τίποτε δεν μπορούσε να σας φτιάξει το κέφι;	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
d. Αισθανόσασταν ηρεμία και γαλήνη;	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
e. Είχατε πολλή ενεργητικότητα;	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
f. Αισθανόσασταν κακοκεφιά και μελαγχολία;	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
g. Αισθανόσασταν εξάντληση;	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
h. Ήσασταν ευτυχισμένος/ευτυχισμένη;	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
i. Αισθανόσασταν κούραση;	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

10. Τις τελευταίες 4 εβδομάδες, για πόσο χρονικό διάστημα επηρέασαν τις κοινωνικές σας δραστηριότητες (π.χ. επισκέψεις σε φίλους, συγγενείς κλπ.) η κατάσταση της σωματικής σας υγείας ή συναισθηματικά σας προβλήματα;

Συνεχώς	Τις περισσότερες φορές	Μερικές φορές	Λίγες φορές	Καθόλου
▼	▼	▼	▼	▼
<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

11. Πόσο ΑΔΗΘΙΝΕΣ ή ΨΕΥΔΕΙΣ είναι οι παρακάτω προτάσεις στη δική σας περίπτωση;

Εντελώς Αλήθεια	Τις περισσότερες φορές αλήθεια	Δεν ξέρω	Τις περισσότερες φορές ψέμα	Εντελώς ψέμα
▼	▼	▼	▼	▼
<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

α. Μου φαίνεται ότι αρρωσταίνω λίγο ευκολότερα από άλλους ανθρώπους..... ☐ 1..... ☐ 2..... ☐ 3..... ☐ 4..... ☐ 5

β. Είμαι τόσο υγιής όσο όλοι οι γνωστοί μου..... ☐ 1..... ☐ 2..... ☐ 3..... ☐ 4..... ☐ 5

γ. Περιμένω ότι η υγεία μου θα χειροτερεύσει..... ☐ 1..... ☐ 2..... ☐ 3..... ☐ 4..... ☐ 5

δ. Η υγεία μου είναι εξαιρετική..... ☐ 1..... ☐ 2..... ☐ 3..... ☐ 4..... ☐ 5

Σας ευχαριστούμε για το χρόνο σας!

Appendix F: SF-36v2

Last Name _____ First Name _____ Date of Visit _____ MRN _____ ICD9-1 _____ ICD9-2 _____

The SF-36v2 Health Survey

Instructions for Completing the Questionnaire

Please answer every question. Some questions may look like others, but each one is different. Please take the time to read and answer each question carefully by filling in the bubble that best represents your response.

EXAMPLE

This is for your review. Do not answer this question. The questionnaire begins with the section *Your Health in General* below.

For each question you will be asked to fill in a bubble in each line:

1. How strongly do you agree or disagree with each of the following statements?

	Strongly Agree	Agree	Uncertain	Disagree	Strongly disagree
a) I enjoy listening to music.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) I enjoy reading magazines	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please begin answering your questions now.

Your Health in General

1. In general, would you say your health is:

Excellent	Very Good	Good	Fair	Poor
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2. Compared to one year ago, how would you rate your health in general now?

Much better now than one year ago	Somewhat better now than one year ago	About the same as one year ago	Somewhat worse now than one year ago	Much worse now than one year ago
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please turn the page and continue.

Office use only

<input type="checkbox"/> pre-op	<input type="checkbox"/> 1 year
<input type="checkbox"/> 6 weeks	<input type="checkbox"/> 2 years
<input type="checkbox"/> 3 months	
<input type="checkbox"/> 6 months	<input type="checkbox"/> Office visit

3. The following questions are about activities you might do during a typical day. **Does your health now limit you in these activities? If so, how much?**

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a) Vigorous activities , such as running, lifting heavy objects participating in strenuous sports	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) Moderate activities , such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c) Lifting or carrying groceries	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d) Climbing several flights of stairs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e) Climbing one flight of stairs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f) Bending, kneeling, or stooping	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g) Walking more than a mile	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h) Walking several hundred yards	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i) Walking one hundred yards	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
j) Bathing or dressing yourself	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

4. During the **past 4 weeks**, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a) Cut down on the amount of time you spent on work or other activities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) Accomplished less than you would like	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c) Were limited in the kind of work or other activities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d) Had difficulty performing the work or other activities (for example, it took extra effort)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

5. During the **past 4 weeks**, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	All of the Time	Most of The time	Some of The time	A little of The time	None of The time
a) Cut down on the amount of time you spent on work or other activities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) Accomplished less than you would like	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c) Did work or other activities less carefully than usual	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

6. During the **past 4 weeks**, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

Not at all ☐ Slightly ☐ Moderately ☐ Quite a bit ☐ Extremely ☐

7. How much bodily pain have you had during the **past 4 weeks**?

None ☐ Very Mild ☐ Mild ☐ Moderate ☐ Severe ☐ Very Severe ☐

8. During the **past 4 weeks**, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all ☐ A little bit ☐ Moderately ☐ Quite a bit ☐ Extremely ☐

9. These questions are about how you feel and how things have been with you during the **past 4 weeks**. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the **past 4 weeks**...

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a) did you feel full of life?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) have you been very nervous?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c) have you felt so down in the dumps nothing could cheer you up?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d) have you felt calm and peaceful?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e) did you have a lot of energy?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f) have you felt downhearted and depressed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g) did you feel worn out?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h) have you been happy?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i) did you feel tired?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

10. During the **past 4 weeks**, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

All of the time ☐ Most of the time ☐ Some of the time ☐ A little of the time ☐ None of the time ☐

11. How TRUE or FALSE is each of the following statements for you?

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
a) I seem to get sick a little easier than other people	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) I am as healthy as anybody I know	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c) I expect my health to get worse	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d) My health is excellent	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

THANK YOU FOR COMPLETING THIS QUESTIONNAIRE!

Appendix G: Demographic and clinical questionnaire

Παρακαλούμε να απαντήσετε στις παρακάτω ερωτήσεις:

- 1) Τύπος Διαβήτη: ☐ Τύπου I ☐ Τύπου II
- 2) Έτος γεννήσεως: _____
- 3) Φύλο: ☐ άνδρας ☐ γυναίκα
- 4) Οικογενειακή κατάσταση:
- ☐ άγαμος ☐ έγγαμος ή με συγγάτοικο ☐ εν διαστάσει ή διαζευγμένος ☐ εν χηρεία
- 5) Τόπος μόνιμης κατοικίας: Δήμος _____
- 6) Ποιες είναι οι γραμματικές σας γνώσεις
- ☐ Δημοτικού ☐ Γυμνασίου ☐ Λυκείου ☐ Πανεπιστημίου
- 7) Επάγγελμα: _____ Θέση – Βαθμός: _____
- 8) Μηνιαίο Οικογενειακό Εισόδημα (€)
- ☐ 0-500 ☐ 501-1000 ☐ 1001-1500 ☐ 1501-2000 ☐ 2001-2500 ☐ 2501-3000 ☐ 3000-
- 9) Πόσων χρόνων ήσασταν όταν διαγνώστηκε ο διαβήτης σας; __ χρόνων
- 10) Ποιο είναι περίπου το επίπεδο της γλυκοζυλιωμένης αιμοσφαιρίνης τον τελευταίο χρόνο;
- ☐ 6.5-7.0 ☐ 7.0 - 7.5 ☐ 7.5 – 8.0 ☐ 8.0 – 8.5 ☐ 8.5 – 9.0 ☐ 9.0 -
- 11) Θεραπεία: ☐ Με ινσουλίνη ☐ Με χάπια ☐ Με δίαιτα μόνο
- 12) Σε σχέση με το διαβήτη σας πόσο συχνά επισκέπτεστε την Κλινική/ Γιατρό σας;
- ☐ Κάθε μήνα ☐ κάθε 3 μήνες ☐ κάθε 6 μήνες ☐ κάθε 1 χρόνο ☐ κάθε 2 χρόνια

- 13) Σε σχέση με το διαβήτη σας έχετε επισκεφθεί τον τελευταίο χρόνο κάποιον από τις παρακάτω ειδικότητες;

☐ ☐ ☐ ☐ ☐

καρδιολόγο οφθαλμίατρο νεφρολόγο ποδίατρο ψυχίατρο ή ψυχολόγο

- 14) Έχει προκαλέσει ο διαβήτης σας κάποια επιπλοκή?

☐ Ναι ☐ Όχι

Εάν Ναι ποια από τις παρακάτω;

☐ ☐ ☐ ☐ ☐ ☐

μείωση έμφραγμα νεφροπάθεια μερικός στυτική άλλη
όρασης ακρωτηριασμός δυσλειτουργία _____

Βαθμός βαρύτητας:

☐ ☐ ☐

ελαφρά μέση σοβαρή

- 15) Τον τελευταίο χρόνο έχετε νοσηλευτεί σε νοσοκομείο (έστω για μια νύκτα) για οποιοδήποτε λόγο;

☐ Ναι ☐ Όχι

Εάν Ναι για πόσες νύκτες; _____ νύκτες

Η αιτία εισαγωγής ήταν:

☐ ☐ ☐

Ο διαβήτης ο διαβήτης και κάτι άλλο κάτι άλλο

- 16) Τον τελευταίο δίμηνο πόσα χρήματα (€) ξοδέψατε από την τσέπη σας για το διαβήτη σας; (Συμμετοχή σε φάρμακα, ταινίες-αναλώσιμα, αμοιβές ιατρών κ.λ.π.)

☐ ☐ ☐ ☐ ☐ ☐ ☐

0-50 50-100 100-150 150-200 200-250 250-300 300-

- 17) Είστε μέλος κάποιου συλλόγου ατόμων με διαβήτη; ☐ Ναι ☐ Όχι

Appendix H: Demographic and clinical questionnaire (in English)

Please answer the following questions:

- 1) **Type of Diabetes:** ☐ Type 1 ☐ Type 2
- 2) **Year of Birth:** _____
- 3) **Gender:** ☐ male ☐ female
- 4) **Marital Status:**
☐ Single ☐ married or partner ☐ separated or divorced ☐ widower
- 5) **Area of permanent residence:** Municipality _____
- 6) **Level of Education**
☐ Primary School ☐ Gymnaseum ☐ Lyceum ☐ University
- 7) **Occupation:** _____ **Position – Rank** _____
- 8) **Monthly Family Income (€)**
☐ 0-500 ☐ 501-1000 ☐ 1001-1500 ☐ 1501-2000 ☐ 2001-2500 ☐ 2501-3000 ☐ 3000-
- 9) **How old were you when your diabetes was diagnosed?** __ years
- 10) **The level of Glycosylated Haemoglobin during the last year was about:**
☐ 6.5-7.0 ☐ 7.0 - 7.5 ☐ 7.5 – 8.0 ☐ 8.0 – 8.5 ☐ 8.5 – 9.0 ☐ 9.0 -
- 11) **Treatment :** ☐ Insulin ☐ Tablets ☐ Diet only
- 12) **In relation to your diabetes how often do you visit your Clinic / Doctor?**
☐ Every month ☐ 3 months ☐ 6 months ☐ once a year ☐ every 2 years

13) How long does it take to come from home to the doctor's? hours

13) In relation to your diabetes have you visited any consultant from the following specialties during the last year?

☐☐☐☐☐

cardiologist

eye-doctor

nephrologist

podiatrist

psychiatrist/psychologist

14) Has your diabetes caused any complication?

☐

yes

☐

No

If Yes which of the following?

☐☐☐☐☐☐

eyesight
reduction

heart attack

nephropathy

partial
amputation

erectile
dysfunction

other:

Degree of severity:

☐

slight

☐

medium

☐

severe

15) During the last year have you been admitted to a hospital (even for one night) for any reason?

☐

Yes

☐

No

If Yes, for how many nights? ____ nights

The cause of admission was:

☐

Diabetes

☐

Diabetes and something else

☐

something else

16) During the last 2 months, how much have you spent (€), out of your pocket, for your diabetes? (Co-payments, strips-consumables, doctor fees etc)

☐☐☐☐☐☐☐

0-50

50-100

100-150

150-200

200-250

250-300

300-

17) Are you a member of any diabetes-patients association ☐ Yes ☐ No

Appendix I: Consent form

ΕΡΕΥΝΑ ΓΙΑ ΤΗΝ ΠΟΙΟΤΗΤΑ ΖΩΗΣ ΑΤΟΜΩΝ ΜΕ ΔΙΑΒΗΤΗ

Αριθμός Κέντρου

Αριθμός Ασθενούς:.....

Ημερομηνία:...../...../2010

Σκοπός της έρευνας αυτής γίνεται για να μετρηθεί η Ποιότητα Ζωής των ατόμων με διαβήτη στην Ελλάδα. Είναι καθαρά επιστημονική έρευνα πανεπιστημιακού επιπέδου και δεν έχει καμία σχέση με ιδιωτικά ή άλλα συμφέροντα.

Το να λάβετε μέρος και να βοηθήσετε την έρευνα είναι αποκλειστικά θέμα δικής σας επιλογής και τυχόν άρνηση σας δεν θα έχει καμία επίπτωση στη θεραπεία σας. Οι ερωτήσεις είναι από ερωτηματολόγια που χρησιμοποιούνται διεθνώς για το σκοπό αυτό και φυσικά οι απαντήσεις είναι εμπιστευτικές. Οτιδήποτε επιπλέον ερώτηση έχετε μπορείτε ελεύθερα να ρωτήσετε το πρόσωπο που σας έδωσε το ερωτηματολόγιο αυτό. Σε περίπτωση που αλλάξετε γνώμη μπορείτε οποιαδήποτε στιγμή να σταματήσετε τη συμπλήρωση.

- 1) Βεβαιώνω ότι διάβασα και κατάλαβα τα παραπάνω
- 2) Συμφωνώ να λάβω μέρος στην έρευνα αυτή
- 3) Συμφωνώ να επικοινωνήσετε μαζί μου στο μέλλον σχετικά με αυτήν την έρευνα

Ονοματεπώνυμο:.....

Διεύθυνση:.....

Τηλέφωνο:.....

Appendix J: Consent form (in English)

RESEARCH ON QUALITY OF LIFE OF PEOPLE WITH DIABETES

Centre Nr.

Patient Nr.

Date:/...../20..

The purpose of this research is to measure the Quality of Life of people with diabetes in Greece. It is purely scientific research at university level and it has not any relation with private or other interests.

To participate and help the investigation is solely a matter of your own choice and your refusal will not have any affect your treatment. The questions are from questionnaires used internationally for this purpose, and of course the answers are confidential. Any further questions you might have feel free to ask the person who gave you this questionnaire. If you change your mind at any time you can stop filling.

- 1) I certify that I have read and understood the above
- 2) I agree to take part in this research
- 3) Agree to contact me in the future in relation to this research

Name:

Address:

Phone:

Appendix K: License Agreement SF-36v2



LICENSE AGREEMENT (OGSR) Office of Grants and Scholarly Research

License Number: PF1-011808-34316

Effective Date: April 22, 2008

Licensee Name: Theodore Pissimissis

Licensee Address: 12 Beaconsfield Place, Newport Pagnell, Buckinghamshire, MK16 0EA, Great Britain (UK)

Royalty Fee: None, because this License is granted in support of the Permitted Use below

Administrative Fee: \$0.00

Term: Beginning on October 1, 2008 and ending on October 1, 2009

Permitted Use: Non-commercial academic research - unfunded – Study "QoL of People with Diabetes Mellitus in Greece"

Licensed Surveys: As indicated in Appendix B attached

Manuals: Licensee must purchase (or have purchased) from QM a copy of the manuals indicated in Appendix B attached

Licensed Material: The Licensed Surveys and the Manuals.

Subject to Licensee's acceptance of and agreement to the terms of this License Agreement (OGSR) (the "Agreement"), including the QualityMetric License (OGSR) Terms and Conditions attached hereto as Appendix A and incorporated herein, and Licensee's payment of the Administrative Fee, QualityMetric Incorporated ("QM"), 640 George Washington Highway, Lincoln, RI 02865, grants to Licensee, and Licensee accepts, a royalty-free, non-exclusive, non-transferable, non-assignable, worldwide license to use, solely for the Permitted Use and during the Term, the Licensed Surveys in the languages indicated above and the accompanying Manuals, and to administer the Licensed Surveys in physical and/or electronic form (and to make up to such number of exact reproductions of the Licensed Surveys to support such administrations) in any combination of the specific Licensed Surveys and authorized languages. Capitalized terms used in this Agreement and not otherwise defined herein shall have the meanings assigned to them in Appendix A.

A third party service provider may administer the Licensed Survey(s) on behalf of the Licensee subject to compliance with Section 2 below.

Licensee hereby accepts and agrees to the terms of this Agreement, as set out above and in Appendix A and B.

Theodore Pissimissis
12 Beaconsfield Place, Newport Pagnell
Buckinghamshire, MK16 0EA
Great Britain (UK)

Signature: _____
Name: _____
Title: _____
Date: _____

➤ For additional information about QM's OGSR, go to <http://www.qualitymetric.com/advancing/> ➤

APPENDIX A

QUALITYMETRIC LICENSE (TRIALS) TERMS AND CONDITIONS

Attached to and Incorporated into License Agreement (OGSR) - 4-1-08

1. Payment Terms

Licensee shall pay the Administrative Fee upon execution of this Agreement, per the enclosed invoice.

2. Use by Students and other Third Parties

Students of Licensee may use and administer the Licensed Surveys, subject to such students' execution of QM's Acknowledgement by Students, available by request. A third party service provider may administer the Licensed Surveys on behalf of Licensee, subject to such third party's execution of QM's Acknowledgement By Agent, available by request. However, in all such cases, Licensee shall not be relieved of its obligations, and Licensee shall be responsible for any breach hereof by such student or third party.

3. No Commercial Use of Data

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This License Agreement shall be effective for the Term, after which this Agreement and the licenses granted hereunder shall terminate. Notwithstanding the foregoing, QM may terminate this Agreement at any time upon written notice in the event of a material breach by Licensee or its personnel of this Agreement.

11. Miscellaneous

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This Agreement constitutes the entire and exclusive agreement between the parties and supersedes all previous communications or agreements, either oral or written, with respect to the subject matter hereof. This Agreement may not be modified or amended except by an instrument in writing signed by both parties.

Any waiver of any breach or default under this Agreement must be in writing and shall not be deemed a waiver of any other or subsequent breach or waiver. Failure or delay by either party to enforce compliance with any term or condition of this Agreement shall not constitute a waiver of such term or condition.

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This Agreement may be executed in multiple counterparts, each of which shall be deemed an original and all of which shall be deemed the same agreement.

* * *

APPENDIX B

QUALITYMETRIC LICENSE (OGSR) - LICENSED SURVEYS AND MANUALS

Attached to and Incorporated into QM - SLA - OGSR - 4-1-08.doc

Licensed Surveys

SF-36v2® Health Survey – Greek (Standard Recall)

Manuals

(563) Users Manual for the SF-36v2® Health Survey